ORIGINAL

CASE CONTROL STUDY OF RESIDENTIAL EXPOSURE TO RADON AND LUNG CANCER AMONG NONSMOKING WOMEN IN MISSOURI

TECHNICAL PROPOSAL

MAO / RFP No. NCI-CP-95654-13

Submitted by:

NCI Master Agreement Holder #NO1-CP-71096

Survey Research Associates, Inc.
6115 Falls Road
Baltimore, Maryland 21209
(301) 377-5660

PERSONS PREPARING PROPOSAL

Diane Monheit, President

Sandi Ezrine, Project Director

Patsy Henderson, Director of Midwest Operations

Joan Cwi, Research Director

Susan Butler, Data Manager/Quality Control Director

SRA Survey Research Associates, Inc.

6115 Falls Road Baltimore, Maryland 21209 (301) 377-5660

December 11, 1989

Ms. Sharon Miller
Contracting Officer
National Cancer Institute
Research Contracts Branch
Executive Plaza South, Suite 620J
9000 Rockville Pike
Bethesda, Maryland 20892

RE: MAO/RFP No. NCI-CP-95654-13

Dear Ms. Miller:

Survey Research Associates, Inc. (SRA) is pleased to submit a proposal to conduct a case/control study in the state of Missouri titled the "Case/Control Study of Residential Exposure to Radon and Lung Cancer Among Nonsmoking Women in Missouri."

We feel that SRA is especially well qualified to undertake all of the tasks associated with the project, namely: maintaining cooperation with the Missouri Cancer Registry and health care facilities, training and monitoring of personnel to abstract medical records, sampling a control population, screening cases and controls for eligibility, administering telephone interviews, conducting a household field visit (including a residential structural survey, placing radon dosi-meters and administering a nutrition questionnaire), harvesting dosimeters, preparing, and tracking and processing all data collected.

From our permanent office in St. Louis, Missouri, SRA is currently conducting the "Case/Control Study of Residential Exposure to Radon" which is the project from which the procedures for this current RFP have been developed.

In performing the work for the current contract, SRA has put together an excellent team of professionals who have been working closely with both NCI and the Missouri Cancer Registry. The prototype study for this RFP has been designed, developed and implemented by an extremely dedicated study team. The key personnel have been successfully working with the NCI project officer for more than two years.

We feel strongly that the expertise and knowledge that have been gained to date on the current project should not be underestimated in the award of this new contract. The methodology for this project is not only complex, multi-phased and of a sensitive nature, it is much more technically demanding than most case/control studies. The numerous details and attention required involve much more than the identification of cases and controls, administration of interviews and placement and harvesting of dosimeters. Individual attention has been given to each and every case and control from the screening process through the telephone interview, field visit, and placement and retrieval of dosimeters. The Study Manager and Field Director work as a team through telephone contact and written correspondence to provide this individual attention. This type of careful attention to each component of the study has resulted in the success of the current project. The award of this contract to another firm will not assure that the success achieved by SRA will be reproduced.

The results achieved to date by SRA, for all phases of the current project, have received acclaim by many investigators in various fields of research.

From our St. Louis office, SRA has also conducted many other projects. Among these is the Health Effects of Environmental Hazards Study in Missouri, which examined the mental health effects of experiencing environmental hazards, including exposure to dioxin and well water contaminated with radioactive wastes.

SRA also has experience collaborating with government registries. SRA has conducted three studies utilizing the Pennsylvania Cancer Registry: Breast Cancer Screening and Detection Programs for the Cancer Control Program, Survey of Cancer Rehabilitation Related Problems and the Study of the Needs of Cancer Patients in the Last Month of Life: As Reported by Their Significant Other. SRA has also collaborated with the Taiwanese Department of Health in the use of its registry of persons who had ingested PCB-contaminated rice oil and the employment of its personnel as interviewers.

As a small business, SRA has been privileged to work on major health-related research projects. Through the success on these projects, we have gained a reputation for high quality performance, excellent project management, fiscal responsibility and good working relationships with funding agency staff. Several studies which achieved high completion rates and high quality data are:

- Breast Cancer Case-Control Project for NCI - 6,500 in-person interviews nationwide - 92% completion;
- Support Services for Environmental Epidemiology and Support Services for New Efforts in Environmental Epidemiology - three 5-year studies for NIEHS which includes interviewing, abstracting, biological specimen collection and storage, laboratory work and analysis of data;
- Breast Milk versus Formula in Primiparae for NICHD - medical record abstracts, baseline and hospital interviews, telephone and in-person follow-up interviews at 1-, 3-, and 7-month intervals for 1,199 primiparae.

The success of any research project includes organized project management, competent staffing, strong quality control operations and commitment to high-quality performance. The team working on the current contract certainly has demonstrated these characteristics. We have achieved a reputation for excellence in these areas and look forward to the opportunity to continue to demonstrate our skills on the Case-Control Study, Residential Exposure to Radon and Lung Cancer Among Nonsmoking Women in Missouri.

Sincerely,

Diane Monheit
President

DM:mpt
Encl.

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TABLE OF CONTENTS

PAGE

EXHIBITS

APPENDICES

APPENDIX A - Curriculum Vitae

APPENDIX B - Sample Computer Report

APPENDIX C - Second Annual Report

APPENDIX D - SRA Office Procedure

APPENDIX E - Client List

APPENDIX F - Experience Chart

APPENDIX G - Study Questionnaires

APPENDIX H - Additional Study Forms

Survey Research Associates, Inc. submits the following response to MAO/RFP NCI-CP-95654-13, Case/Control Study of Residential Exposure to Radon and Lung Cancer Among Nonsmoking Women in Missouri.

A. Statement of Work

1. Background Information

The National Cancer Institute (NCI) began researching the risk of lung cancer associated with Radon exposure in the home during a data collection effort begun in 1987 under the title of "Case/Control Study, Residential Exposure to Radon." This study, still in progress, is being conducted by the incumbent, Survey Research Associates (SRA). The purpose of the current study, as well as the proposed study, is to assess the risk of lung cancer associated with Radon exposure in the home, independent of the effects of occupational exposure and cigarette smoking.

The data collected to date along with the data to be collected under this new proposal are significant for many reasons. Understanding the risk of lung cancer from exposure to indoor Radon is important in terms of implementing far-reaching public health policy decisions regarding the allocation of funds to identify and correct residences with high concentrations of Radon in order to protect current and future residents from lung cancer.

Epidemiologic studies have demonstrated that high-level Radon exposure experienced by miner populations poses a serious lung cancer risk.[1,2] In recent years there has been increasing interest in assessing the lung cancer risk posed to the general population by lower levels of indoor Radon exposure.[3,4] Extrapolating lung cancer risk estimates derived from studies of high level occupational exposure of miner populations to the low level exposure in the general population leaves numerous uncertainties.[4,5] Previous studies attempting to evaluate the risk of exposure to indoor Radon have been faulty in that they have not been sufficiently large, have not had accurate measures of lifetime exposures, and have not controlled for potential confounders.[6]

The current study, along with the proposed study, attempts to correct these major problems that belabored past researchers. By using the resources of the Missouri Cancer Registry, non-smoking women who develop lung cancer can be identified by using rapid case ascertainment and quickly interviewed, while most are still living. By supplementing the original study, the power of analysis can be enchanced by increasing the sample size from about 280 non-smoking female lung cancer cases to about 600. Subsequently, control cases can be increased from about 560 to 1,400. This larger sample size should be convincing in addressing the issue of whether or not indoor Radon poses substantial risk for lung cancer.

2. Objectives

The primary objective of the Case/Control Study of Residential Exposure to Radon and Lung Cancer Among Nonsmoking Women in Missouri is to collect additional data which will permit NCI to assess the risk of lung cancer associated with Radon exposure in the home, independent of the effects of occupational exposure and cigarette smoking. These data will be collected throughout the state of Missouri from both a sample of female lung cancer patients who have never smoked and an age-group matched sample of a general population of female controls who

have never smoked. Data collection methods will include identifying eligible case and control subjects, medical record abstracting, telephone interviewing, distributing and collecting passive Radon dosimeters, and residential field surveying.

To provide ongoing support to NCI in achieving its objectives in this new Case/Control Study of Residential Exposure to Radon, SRA proposes to continue to provide, from its permanent office located in St. Louis, Missouri, the following services:

- Coordinate the rapid case ascertainment system within the Missouri State Cancer Registry;
- Monitor the abstraction of medical record data needed for NCI analysis and the identification of eligible cases;
- Code medical record abstract forms;
- Locate and screen a pool of eligible general population controls using Missouri Department of Motor Vehicles (DMV) and Health Care Financing Administration (HCFA) files;
- Complete telephone interviews with 1,160 study subjects (cases, controls, and next of kin);
- Conduct a construction field survey of all current and former homes of cases and controls completing a telephone interview;
- Have cases and controls complete a nutrition questionnaire at the time of the field survey;
- Dispense and collect two passive Radon dosimeters from current and previous residences of all cases and controls;
- Provide computerized tracking reports on all data collection activities as well as narrative monthly, semi-annual and final reports;
- Take part in monthly conference calls with study investigators;
- Plan three Pathology Review Panel meetings;
- Edit, code, data enter and clean all collected data;
- Deliver clean data tapes that meet NCI specifications; and
- Provide decision logs on editing/coding decisions and study activities.

In addition to extending those activities listed above currently being successfully completed by SRA, SRA will also make arrangements for a pathology review panel to review and code the pathology material collected for study cases.

The anticipated time period for the above activities will be July 1, 1990 to June 30, 1991. EXHIBIT A.1 is a timeline which depicts the sequence of the efforts required for the project. EXHIBIT A.2 is a chart of the projected work effort by year.

EXHIBIT A.1

CASE CONTROL STUDY OF RESIDENTIAL EXPOSURE TO RADON AND LUNG CANCER
AMONG NON-SMOKING WOMEN IN MISSOURI

TIMELINE

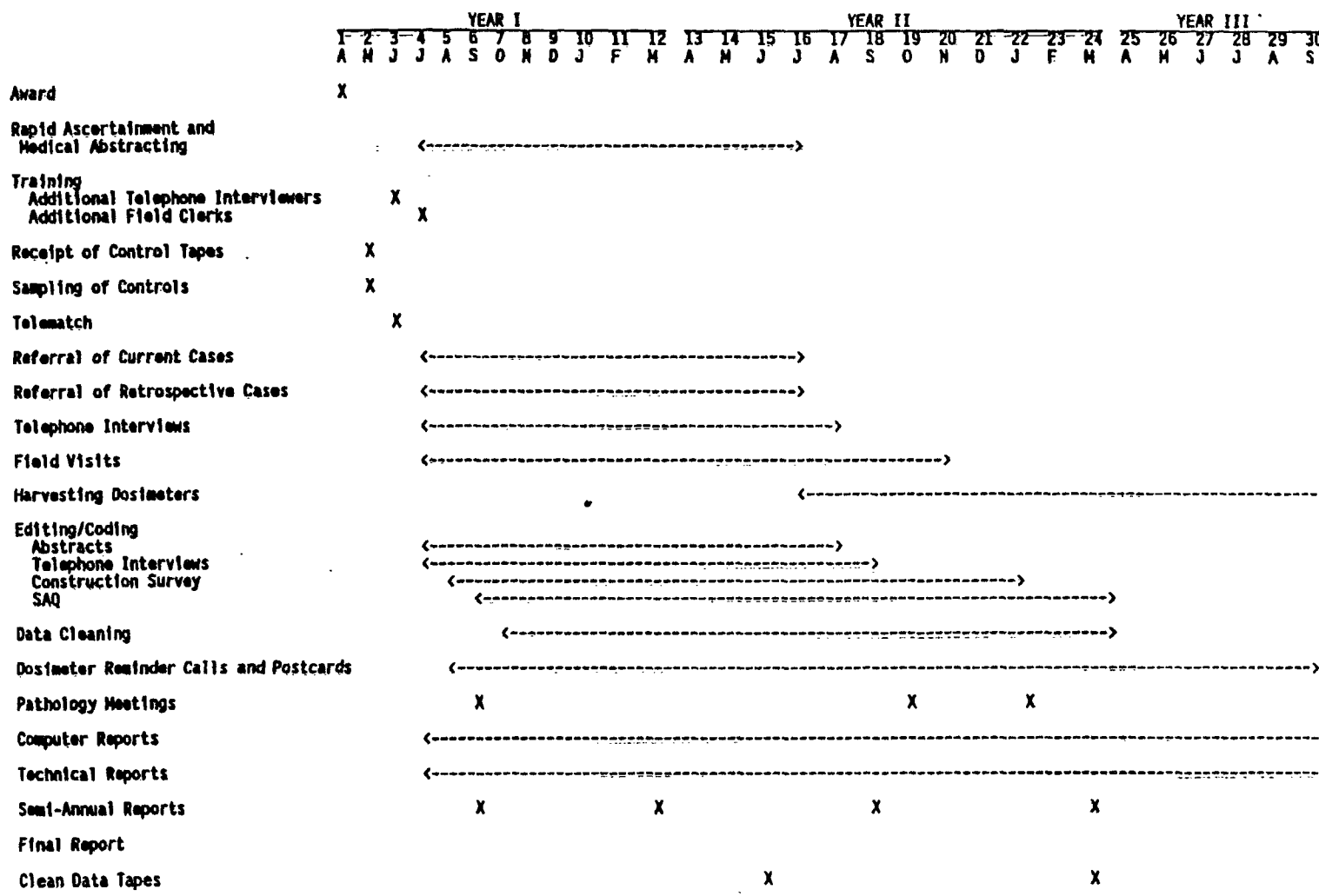

EXHIBIT A.2

PROJECTED WORK COMPLETED PER YEAR

TASK	YEAR I	YEAR II	YEAR III	TOTAL
Abstracting				
Prospective Cases	213	72		285
Retrospective Cases	405	136		541
Screening				
Cases	618	208		826
Controls	2246	750		2996
Interviewing				
Telephone Interviews	870	290		1160
Construction Surveys	1000	1480		2480
Nutrition Questionnaires	700	344		1044
Editing				
Abstracts	210	110		320
Telephone Interviews	800	360		1160
HH Surveys	800	1680		2480
Nutrition Questionnaires	700	344		1044
Data Cleaning				
Abstracts	210	110		320
Telephone Interviews	800	360		1160
Constuction Surveys	800	1680		2480
Nutrition Questionnaires	700	344		1044
Detectors Harvested		1720	2437	4157

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1 Howe, G.R., C.N. Rama, H.B. Newcombe, A.B. Miller and J.D. Abbatt. "Lung Cancer Mortality (1950-1980) In Relation to Radon Daughter Exposure in a Cohort of Workers at the Eldorado Beaverlodge Uranium Mine" Journal of the National Cancer Institute 77(2): 357-362, 1986.

2 Saccomanno, G., C. Yale, W. Dixon, O. Auerbach, and G.C. Huth. "An Epidemiological Analysis of the Relationship Between Exposure to Rn Progeny, Smoking, and Bronchogenic Carcinoma in the U-Mining Population of the Colorado Plateau - 1960-1980" Health Physics 50(5): 605-618, 1986.

3 Edling, Christer M.D., Hans Kling, and Olav Axelson, M.D. "Radon In Homes - A Possible Cause of Lung Cancer" Scandinavian Journal of Work and Environmental Health 10:25-34, 1984.

4 Hofmann, Werner, Robert Katz, and Zhang Chunxiang. "Lung Cancer Risk At Low Doses of Alpha Particles" Health Physics 51(4): 457-468; 1986.

5 Ginevan, Michael E. and William A. Mills. "Assessing the Risks of Rn Exposure: The Influence of Cigarette Smoking" Health Physics 51(2): 163-174, 1986.

6 Cohen, Bernard L. "A National Survey of 222Rn In U.S. Homes and Correlating Factors" Health Physics 51(2), 175-183, 1986.

B. Workplan

As incumbent, much of the workplan outlined below describes procedures already in place. SRA's success in conducting this study to date and achieving such high response rates comes from the expertise of the office and field staff executing the study. The staff are permanent SRA employees that would not be available to a new contractor. Part of their achievement comes from perseverance in following leads in identifying people and residences as well as a great deal of attention to detail and individuals. This attention to detail is especially important in attempting to place dosimeters, where the endless variations in living circumstances have to be individually addressed in order to achieve high success rates.

In responding to the MAO/RFP NO. NCI-CP-95654-13, SRA has utilized our experience from the MAO NO. NCI-CP-71096-01, Case/Control Study of Residential Exposure to Radon, which was awarded to SRA on September 30, 1987 and will expire September 29, 1990. The projections made in this proposal are based on statistics for the current project through October 31, 1989.

1. Tumor Registry Coordinator (Missouri Cancer Registry Liaison)

The Tumor Registry Coordinator (liaison) is the link between the Missouri Cancer Registry and the data collection effort. Without this person, identification of cases would be difficult and would be completed at a much slower and less accurate rate. SRA has a liaison working on the current contract who would continue in this capacity for the new contract. (See Section C). The Tumor Registry Coordinator works closely with the Missouri Cancer Registry in Columbia, Missouri under the combined direction of SRA and Ross Brownson, Ph.D., Division Director of Chronic Disease Prevention and Health Promotion, Missouri Department of Health.

a. Contact with Missouri Cancer Registry

Since SRA currently has an excellent working relationship with the Missouri Cancer Registry, this initial contact will not have to be made. A letter in support of SRA by Dr. Brownson is shown as EXHIBIT B.1. The ethical and practical procedures required by the Missouri Cancer Registry for this study have already been met.

Useful information and forms regarding the registry is available in the Missouri Division of Health Cancer Registry Brochure (EXHIBITS B.2, B.3, B.4, B.5).

b. Identification of Cases and Abstraction of Records

In order to identify all female lung cancer cases in a timely manner, the Tumor Registry Coordinator will continue to maintain regular telephone communication with tumor registars, hospitals and doctors offices. Approximately 300 calls per month are made to 138 Missouri acute care centers responsible for maintaining lung cancer patient enrollment and treatment records for the state cancer registry. These calls are necessary not only to identify the cases as they are picked up by the facility, but also to check on abstracting information.

For the current project, the Tumor Registry Coordinator has identified the appropriate personnel at each facility who supply her with the requisite information for identifying prospective cases. In performing this task, the liaison checks the monthly computer printout of all female lung cancer cases entered

- 1 -

EXHIBIT B.1

Missouri Department of HEALTH

John Ashcroft
Governor

Robert Harmon, M.D.
Director

Division of Chronic Disease Prevention and Health Promotion
201 Business Loop 70 West
Columbia, MO 65203

314/876-8100
FAX 314/876-8104

November 26, 1989

Sandi F. Ezrine
Project Director
Survey Research Associates, Inc.
6115 Falls Road
Baltimore, MD 21209

Dear Sandi:

I am pleased to write in support of your application for a Master Agreement Award to continue work on the study of residential radon exposure and lung cancer among nonsmoking women in Missouri.

The staff of the Missouri Cancer Registry is enthusiastic about continuing this important study. We agree to continue to assist your staff by providing timely and accurate data on lung cancer cases that fit the criteria of the study.

Survey Research Associates has done an outstanding job during the first two years of the study and I am confident that this high quality work will continue should your proposal be funded.

Best of luck with the application!

Sincerely,

Ross C. Brownson, Ph.D.
Director
Division of Chronic Disease Prevention
and Health Promotion

cc: Dr. Jian Chang

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EXHIBIT B.2

MISSOURI DEPARTMENT OF HEALTH

MISSOURI CANCER REGISTRY: INITIAL

RCN *1

*2 Name (Last, First, Middle) 2a (Maiden, Spouse's Name)

*3 Permanent Residence (No. & Street, Town, County, State, Zip Code, Phone No.)

4 Accession No. *8 Race *9 Sex *13 Residence at B.

*5 Chart No. 10 Admission Date or OPD *13a Primary Past Residence

*6 Social Security No. 11 Last Contact Date *14 Birth Date

7 Attending Physician *12 Residence at DX ____ Age at DX

*15 Primary Site *(Specify)

*16 Histologic Type / Grade *(Specify)

*17 Original Diagnosis Date

*18 Basis of DX (HISTOLOGY): Autopsy; Histology; Cytology; X-ray; Exploration; Clinical only

19 Sequence Number 20 Laterality 21 Recurrence? 22 Analytic? 23 Biopsy?

*24 Stage at this Admission *(Describe Extent) (Stage Lymphomas I, II, III, IV)
- None
- In-situ
- Localized
- Regional, direct extension
- Regional nodes
- Regional, direct extension and nodes
- Distant metastases
- Widely disseminated

	Clinical	Pathologic
25 T		T
N		N
M		M
a cTNM		pTNM

*26 Tumor-Directed RX (Explain)

27 Rx Dates

*27a Unusual Toxic Exposu

28 Reasons no RX (Explain)

Previous RX (Specify):

Hospital:

Original Stage 29 30

31 RX Types 32 Dates

*33 Vital Status

DEATH: Place; Causes Immediate; Underlying:

34 Autopsy? 35 Ca Status 36 Date 37

*39 Pregnancies/ Live Births (Circle)

*40 Alcohol

*41 Tobacco

Family History Relationship Site *38

Personal History Site Year *38a

Optional a b c d

*42 Lifetime Occupation

*42a Type of Industry

*42b Years in Occupation

pack years

Signature Date

2025792022

EXHIBIT B.3

MISSOURI DEPARTMENT OF HEALTH

MISSOURI CANCER REGISTRY: FOLLOWUP

RCN

Primary Site

Name _____ DX Date _____ Site _____

Histologic Type

Chart No. _____ Accession ☐☐☐☐☐☐ ☐ Histology _____ /☐

FOLLOWUP SOURCE	FOLLOWUP SOURCE
Name	Name
Address	Address

OTHER HOSPITALS FOLLOWING

Method of Contact
1. Visited this hospital
2. Other hospital or Doctor's office
3. Letter or phone contact with patient or relative
4. Death certificate/ MCR/Death Match
5. Other

Vital Status
1. Alive, no evidence or complete remission of cancer
2. Alive, with any cancer
3. Alive, cancer status unknown
4. Dead

Rx — Letter and number
N. None
S. Surgery
R. Radiation
C. Chemotherapy
H. Hormones
I. Immunotherapy
O. Other

	Contact Date First / Last	Method of Contact	Subsequent Primaries?	Recurrence?	Metastasis?	Vital Status	Quality of Survival	RX	Starting Date / Ending Date	RX	Starting Date / Ending D.
1. ☐	/								/		/
Remarks								Optional			
2. ☐	/								/		/
Remarks								Optional			
3. ☐	/								/		/
Remarks								Optional			
4. ☐	/								/		/
Remarks								Optional			
5. ☐	/								/		/
Remarks								Optional			
6. ☐	/								/		/
Remarks								Optional			

INFORMATION

Place _____

Causes (Immediate) _____

(Underlying) _____

☐ Autopsy?

☐ Ca Status

Date ☐☐ ☐☐ ☐☐

☐☐☐☐ /☐☐

CANCER STATUS (AT DEATH)

0 — No evidence of cancer or a benign neoplasm present.
1 — THIS cancer present, even if other cancers present.
2 — No evidence of THIS cancer, but ANOTHER cancer prese
3 — Cancer present at death, but can't be established whethe was this or another cancer

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EXHIBIT B.4

MCR-318 and MCR-319 Code Sheet

8. RACE
W-White
B-Black
3-Am. Indian
4-Oriental
5-Hispanic
6-Other.

9. SEX
M-Male
F-Female
3-Other (transsexual/hermaphrodite)

20. LATERALITY
0-Not a paired organ or unknown site
1-Right organ involvement only
2-Left organ involvement only
3-Only one organ involved, right or left unspecified
4-Both organs involved simultaneously
5-Left organ involved after previous involvement of right organ
6-Right organ involved after previous involvement of left organ
7-Both organs involved at different times, but unknown which was first
9-Paired organ, but lateral involvement unknown

28. REASON NO RX
0-Only observation at this time
1-Patient/family refused
2-Concurrent disease
3-Not indicated, Ca too extensive
4-Patient expired
5-Patient left
6-To return later for Rx
7-To be transferred for Rx
8-Patient's advanced age precludes Rx

33. VITAL STATUS
1-Alive, no clinical evidence or complete remission of cancer or a benign neoplasm
2-Alive, with ANY cancer
3-Alive, cancer status unknown
4-Dead

39. PREGNANCIES/LIVE BIRTHS (FEMALE PATIENTS ONLY)
If both are available code pregnancies. Use 0-8 for coding number, use 8 if more than 8. Use 9 for unknown. Circle pregnancies or live births to indicate use.

40. ALCOHOL (# OF DRINKS OR BEERS)
0-None
1-Light (< 2 per day)
2-Moderate (2-6 per day)
3-Heavy (> 6 per day)
4-Drinking mentioned, quantity unknown
5-Former moderate to heavy drinker
9-Unknown

FOLLOW-UP QUALITY OF SURVIVAL
1-Capable of usual activities
2-Incapable of usual activities
3-Activities severely limited - requires nursing care
4-Dead
9-Unknown

CASES NOT REPORTED TO MCR
questionable suggested
possible equivocal

19. SEQUENCE NUMBER
0-One primary only
1-First of two or more primaries
2-Second of two or more primaries
3-Third of three or more primaries
4-Fourth of four or more primaries
5-Fifth of five or more primaries
6-Sixth or later primary
7-Basal and squamous cell skin cancers
8-Nonreportable (benign) primary
9-Unspecified sequence number

PAIRED ORGAN SITES (FOR USE WITH ITEM 20)

adrenal gland	lung
arm	maxillary sinus
breast	middle ear
bronchus	nipple
carotid body	ovary
eustachian tube	parathyroid gland
eye	parotid gland
ear	pleura
fallopian tube	seminal vesicle
foot	submaxillary gland
frontal sinus	testis
hand	tonsil
kidney parenchyma	tonsillar pillar
leg	ureter

38. FAMILY HISTORY
1-Father
2-Mother
3-Brother
4-Sister
5-Aunt or Uncle
6-Grandparent
7-Spouse
8-Son or Daughter

35 CANCER STATUS (AT DEATH)
0-No evidence of cancer or a benign neoplasm present
1-THIS cancer present, even if other cancers present
2-No evidence of THIS cancer, but ANOTHER cancer present
3-Cancer present at death, but can't be established whether it was this or another cancer
9-Cancer status unknown

41. TOBACCO
0-None; never smoked
1-Former smoker
2-Light smoker (< 1 per day)
3-Moderate smoker (1-2 per day)
4-Heavy smoker (> 2 per day)
5-Smoker; amount unknown
6-Uses other forms tobacco (cigar, snuff, etc
9-Unknown

ACoS REPORTABLE SKIN CANCERS

anus	labia	prepuce
clitoris	lip	scrotum
eyelid	penis	vulva

CASES TO BE REPORTED TO MCR
probable compatible with
suspected consistent with
suspicious

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EXHIBIT B.4
(cont.)

COUNTY		COUNTY		COUNTY		STATE	
001	Adair	087	Holt	173	Ralls	FL	Florida
003	Andrew	089	Howard	175	Randolph	GA	Georgia
005	Atchison	091	Howell	177	Ray	HI	Hawaii
007	Audrain	093	Iron	179	Reynolds	ID	Idaho
009	Barry	095	Jackson	181	Ripley	IL	Illinois
011	Barton	097	Jasper	183	St. Charles	IN	Indiana
013	Bates	099	Jefferson	185	St. Clair	IA	Iowa
015	Benton	101	Johnson	187	St. Francois	KS	Kansas
017	Bollinger	103	Knox	189	St. Louis	KY	Kentucky
019	Boone	105	Laclede	193	Ste. Genevieve	LA	Louisiana
021	Buchanan	107	Lafayette	195	Saline	ME	Maine
023	Butler	109	Lawrence	197	Schuyler	MD	Maryland
025	Caldwell	111	Lewis	199	Scotland	MA	Massachusetts
027	Callaway	113	Lincoln	201	Scott	MI	Michigan
029	Camden	115	Linn	203	Shannon	MN	Minnesota
031	Cape Girardeau	117	Livingston	205	Shelby	MS	Mississippi
033	Carroll	119	McDonald	207	Stoddard	MO	Missouri
035	Carter	121	Macon	209	Stone	MT	Montana
037	Cass	123	Madison	211	Sullivan	NE	Nebraska
039	Cedar	125	Maries	213	Taney	NV	Nevada
041	Chariton	127	Marion	215	Texas	NH	New Hampshire
043	Christian	129	Mercer	217	Vernon	NJ	New Jersey
045	Clark	131	Miller	219	Warren	NM	New Mexico
047	Clay	133	Mississippi	221	Washington	NY	New York
049	Clinton	135	Moniteau	223	Wayne	NC	North Carolina
051	Cole	137	Monroe	225	Webster	ND	North Dakota
053	Cooper	139	Montgomery	227	Worth	OH	Ohio
055	Crawford	141	Morgan	229	Wright	OK	Oklahoma
057	Dade	143	New Madrid	510	St. Louis City	OR	Oregon
059	Dallas	145	Newton			PA	Pennsylvania
061	Daviess	147	Nodaway			RI	Rhode Island
063	DeKalb	149	Oregon		STATE	SC	South Carolina
065	Dent	151	Osage			SD	South Dakota
067	Douglas	153	Ozark	AL	Alabama	TN	Tennessee
069	Dunklin	155	Pemiscot	AK	Alaska	TX	Texas
071	Franklin	157	Perry	AZ	Arizona	UT	Utah
073	Gasconade	159	Pettis	AR	Arkansas	VT	Vermont
075	Gentry	161	Phelps	CA	California	VA	Virginia
077	Greene	163	Pike	CO	Colorado	WA	Washington
079	Grundy	165	Platte	CT	Connecticut	WV	West Virginia
081	Harrison	167	Polk	DE	Delaware	WI	Wisconsin
083	Henry	169	Pulaski	DC	District of Columbia	WY	Wyoming
085	Hickory	171	Putnam				

43. OPTIONAL CODING DESCRIPTION

SCHEME NUMBER		ITEM DESCRIPTION		UNITS USED OR CODING SOURCE
1.	INITIAL	A.		
		B.		
		C.		
		D.		
2.	INITIAL	A.		
		B.		
		C.		
		D.		
3.	FOLLOW	A.		
		B.		
4.	FOLLOW	A.		
		B.		

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WHAT ABOUT CONFIDENTIALITY?

Strict policies and procedures have been developed to serve as guidelines for maintenance of confidentiality and disclosure of data. Hospitals participating in MCR retain control over their data. Access to confidential information on summary data is allowed only by agreement with participating hospitals.

Data collected on each patient include:

- Patient identification
- Site of disease(s)
- Tumor histology
- Stage or extent of disease(s)
- Treatment performed or initiated
- Current status of patient
- Length of survival
- Family history of cancer
- Tobacco and alcohol use
- Occupation and industry
- Unusual toxic exposure

IN SUMMARY . . .

The Missouri Cancer Registry serves a twofold purpose:

1. It is a tax-supported service to individual hospitals and their health care personnel.
2. It maintains a centralized database documenting cancer incidence.

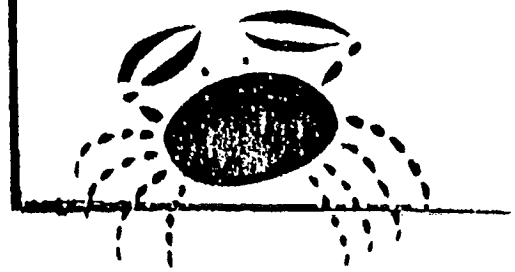
FOR MORE INFORMATION CONTACT:

Missouri Cancer Control Program
Missouri Cancer Registry
Business Loop 70 & Garth Avenue
Columbia, MO 65201
(314) 875-2218 or 2219

Department of Social Services
MISSOURI DIVISION OF HEALTH
Bureau of Chronic Diseases

Rev. 10/84

Missouri Division of Health Cancer Registry



WHAT IS A REGISTRY?

A cancer registry is a system for collection, storage, analysis, and interpretation of information on cancer and cancer patients. It may include data on premalignant lesions and certain benign tumors as well as on malignant neoplasms. Cancer registries are either hospital-based or centralized; the difference lies in scope.

The Hospital-Based Registry: The hospital-based cancer registry may be an autonomous unit or a section of another department. Using information obtained from medical records, the hospital registry provides immediate access to cancer data—such as exact number of diagnoses in a given time period or relative frequency of cancers by site.

A hospital-based survival registry allows for active lifetime follow-up of cancer patients diagnosed or treated in that hospital. Registry data can also assist in evaluation of survival rates. Diagnosis, treatment, and staging data can provide persuasive documentation for additional hospital personnel, equipment, and facilities.

The Central Registry: A central cancer registry depends on data obtained from hospital-based registries or other sources. A statewide system maintains data on a large enough population to make statistically significant analyses of cancer incidence and prevalence. As research turns more and more to investigation of environmental, occupational, and lifestyle factors in cancer incidence, the population-based registry's role in epidemiological assessment becomes increasingly important. Clinically, the central registry can play a significant role in providing analyses of data on individual patients or groups of patients to assess efficacy of diagnostic and treatment practices.

THE MISSOURI CANCER REGISTRY

The Missouri Cancer Registry (MCR) is a central cancer registry system operating since 1972 in cooperation with hospitals throughout the state. MCR is a major component of the Missouri Cancer Control Program within the Bureau of Chronic Diseases of the Missouri Division of Health. The Program maintains liaison with the American Cancer Society, the American College of Surgeons, and with national, state, and regional medical record and tumor registrar associations.

In 1983, a bill mandating cancer-incidence reporting on every hospitalized cancer case was signed into law. The law provides shared responsibility for reporting between the physician, who makes required information available to the hospital chief executive officer, who reports this information to MCR. Data on occupation, family history, personal habits and unusual toxic exposures are among the required items. Subsequent reports on each cancer case are not required by law; however, MCR encourages hospitals to follow their patients annually and to voluntarily submit follow-up results.

WHAT DOES THE MISSOURI CANCER REGISTRY PROVIDE?

Data Processing: Provides a computerized system for storage and retrieval of cancer specific information; generates special listings and reports as requested by participating hospitals

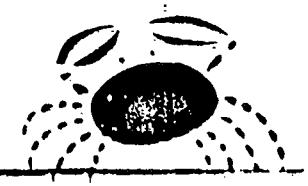
Consultation: Serves as a resource to hospitals initiating registry operation; provides annual workshops for hospital-based registrars; consults with hospital-based registrars on routine problem solving and data quality assurance; assists in meeting requirements for approval of a Hospital Cancer Program by Americ College of Surgeons.

Materials: Provides free of charge all forms and many of the reference materials required for hospital-based registry operation.

Evaluation of Care: Can assist in systematic follow-up of cancer patients; permits each hospital to evaluate its diagnostic and treatment practices.

Administrative Planning: Establishes a data base for justification of hospital facilities, equipment, and personnel involved in cancer care.

Statewide Cancer Database: Examines trend in cancer incidence, therapy, and patient survival; provides data for epidemiological studies to identify environmental risk factors; assists in evaluation of overall effectiveness of public interventions such as education and screening programs.



From: MISSOURI CANCER UPDATE, Volume 1, Number 1 January 1987
Published by American Society

From the Editor:

We are pleased to inaugurate this first issue of Missouri Cancer Update. This leaflet, to be inserted into each issue of CA—A Cancer Journal for Clinicians will focus on topics, activities, and interests of health professionals within the State of Missouri and the Missouri Division of the American Cancer Society.

The contributor for this edition of Missouri Cancer Update is Dr. Jian C. Chang, Research Analyst for the Missouri Cancer Registry. Dr. Chang reviews the history and scope of the Registry and its contributions in the collection and analysis of "Cancer Statistics".

Q. Scott Ringenberg, MD
Editor

Missouri Cancer Registry Jian C. Chang, M.D.

A cancer registry is a data collection and dissemination system which identifies characteristics of cancer patients.

The Missouri Cancer Registry (MCR) began in 1972 under contract with the Cancer Research Center in Columbia, Mo. This contract was funded by the State Department of Health (DOH) until 1978, when the Registry became a part of the DOH.

The Missouri Cancer Registry experienced a slow and steady growth between 1972 and 1983. This growth occurred during a period of voluntary cancer reporting by Missouri hospitals. However, state legislation passed in 1983 made cancer incidence reporting mandatory for all Missouri hospitals and designated the Cancer Registry as the statewide centralized registry system.

All cancer patients seen, diagnosed, or treated by a physician at a hospital, are to be reported to the Cancer Registry. The minimum data items required on each patient include:

Assigned hospital code number, patient's name, medical record number, race, sex, birth date and social security number; patient's residence at birth, at diagnosis, primary past residence and present residence; primary anatomic site and histologic type in English and ICD O code, basis of diagnosis, stage at this admission and treatment of cancer; personal and family history of cancer with ICD-O site coding, vital status of patient, unusual toxic exposures, number of pregnancies or live births, level of alcohol and tobacco use, primary past occupation, type of industry and number of years employed in the industry.

The legislation has significantly increased the level of cancer incidence reporting by Missouri hospitals. The Cancer Registry currently abstracts approximately 70 percent of the cancer cases in Missouri. This estimate is based on current levels of reporting and the expected number of cases, as published in "Cancer Facts and Figures" by the American Cancer Society. However, hospital reporting is expected to increase during the next year to include smaller short-term hospitals.

Of the 138 hospitals regularly reporting to the Cancer Registry, 70 hospitals have survival registries (i.e., the registry insures annual life-time follow-up of each patient with cancer).

The primary purpose of the Missouri Cancer Registry is to provide a quality statewide data base. The information collected is used by DOH for examining trends in cancer incidence, conducting epidemiological studies to identify environmental risk factors and evaluating the overall effectiveness of cancer control interventions (such as education and screening programs). The Registry is currently collaborating with the National Cancer Institute on two such studies. These include 1) A study of Lung Cancer Histologic Subtypes, Occupation and Smoking in Missouri, and 2) Lung Cancer in Missouri Among Non-smokers. Both studies have utilized the unique data items available from the Cancer Registry (e.g. tobacco, family history and occupational data items).

Contributions to "Missouri Cancer Update" are solicited by the editors; prospective contributors are encouraged to contact the editors. Future topics for upcoming issues include:

- "Trouble in a Pinch" - Health Hazards of Smokeless Tobacco and the Activities of the Missouri Division Smokeless Tobacco Task Force
- "Xeromammography for Screening of Breast Cancer" and Activities of the Missouri Division Mammography Task Force

Editors:

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Anne Remington, RN, Vice President of Medical Affairs/Public Issues, Missouri Division, American Cancer Society, P.O. Box 1066, Jefferson City, Missouri (314) 893-4800

into the system at the end of each month to make sure she has identified all eligible cases. Any that are missed, are retrieved at this time. Using these procedures, approximately 45 cases per month are currently being identified.

Identifying the 1987 and 1986 retrospective cases will require different techniques. The 1987 cases (about 400) have to be manually pulled from file cabinets, copied, coded if necessary, and refiled. The 1986 cases are on microfilm and need to be read and pertinent information copied onto an abstract form.

During monthly circuit riding trips, the liaison will continue to have the tumor registrar at each of the large hospitals (over 50 acute care beds) pull the medical records for all female lung cancer cases. She will then review the record and complete the abstract form on site which includes obtaining information for disease and staging coding. The International Classification of Diseases for Oncology (ICD-O) for disease coding and the SEER Summary Staging Guide for staging coding are utilized.

When the circuit riding is performed at small hospitals (under 50 acute care beds), the director of medical records pulls all of the cancer cases in preparation for the liaison visit. At these visits the liaison reviews each chart and completes the abstracts for eligible females.

Copies of abstracts for both smoking and nonsmoking lung cancer cases are kept in separate files. Only those who are eligible as non-smoking, former smokers or smoking history unknown are copied and referred to SRA for screening.

c. Obtaining Cooperation of Other Agencies and Officials

For the current contract, the Tumor Registry Coordinator has contacted tumor registrars, directors of medical records and physicians of cancer cases to explain the study and obtain their cooperation. At this point in time, we have obtained full cooperation throughout the state of Missouri.

For the current contract, many contacts were made with various agencies, newspapers, television stations, local departments of health, and the Better Business Bureau to provide local awareness of the legitimacy of the study. As in the past, future inquiries will be directed to the Study Manager and/or Dr. Brownson at the Cancer Registry.

d. Arranging Communications with Other Agencies and Officials

The Missouri Cancer Registry mails a bulletin to all Missouri hospitals to provide information about changes in the registry and update information about research projects. During the development phase of the project these bulletins were used to provide information about the Radon Study. At the state meeting of tumor registrars, the Radon Study was discussed by Dr. Brownson. When similar opportunities arise during the execution of this new study, SRA will continue to take advantage of the opportunity to keep Missouri health care facilities apprised of our work.

e. Attending and Reporting on Meetings

Through her meetings with state organizations and officials and her monthly conference calls with the investigators, the Tumor Registry Coordinator will keep the study team apprised of difficulties in case ascertainment. New directives

are then issued based on this information and the liaison makes the requisite changes. The circuit riding and routine telephone contacts are a result of implementing such procedures. The liaison will continue to alter procedures as indicated to achieve the goals for the project.

f. Acting as Ongoing Liaison between Registry and NCI

The liaison reports to the SRA Study Manager. The Study Manager then brings any problems to the attention of the research team. This includes SRA's Project Director, Dr. Brownson (Division Director of Chronic Disease Prevention and Health Promotion of the Missouri Department of Health) and Michael Alavanja, Ph.D. (NCI Project Officer). Drs. Brownson and Alavanja, in turn, report to NCI.

2. Accessing Study Materials and Manuals

a. Transitional Activities

This section of the proposal concerns activities which firms other than the incumbent would need to take to make the transition. Essentially, a new firm would have to contact SRA to obtain study materials currently in use, be trained on operating procedures, and adapt computer programs being utilized for tracking and data cleaning. These transitional activities include:

- obtaining copies of all printed materials including screeners, questionnaires, Cancer Registry Referral Form, abstract forms, tracking forms, coding forms, advance and conversion letters, reminder postcards and letters, dosimeter retrieval letters, dosimeter reading analysis letters, procedural training manuals, editing and coding specification and computer software instruction for tracking and data cleaning programs;
- Attendance at a two-day training session at SRA's St. Louis office to be instructed on the use of the above-mentioned items; and
- Adapting the above items to their own in-house use.

As all technical staff on the current radon project are permanent professional SRA staff members, a new contractor would have to allocate manhours for a new Project Director, Study Manager, Quality Control Coordinator, Programmer and Data Manager to familiarize themselves with the intricacies of this complex, multifaceted project.

In addition, a new firm will have to recruit, hire and train a Missouri Tumor Registry Coordinator (liaison), supervisory and office staff, telephone interviewers and structural assessment field clerks. More than likely, the new firm will also have to set up an office, which is unlikely to be as fully equipped as SRA's permanent office in St. Louis, Missouri, from which the study is managed.

SRA, as incumbent, will not have to assume these costs. All of the above mentioned activities are operational and the personnel are trained and actively engaged in the project. In addition, SRA has already demonstrated its ability to achieve high completion rates in all of the activities associated with this complex project.

The current study is succeeding when other similar attempts have failed because of the individualized treatment of each case. This individualized treatment includes the use of dozens of letters addressing each unique dosimeter placement situation, knowledge of major landlord and management companies in Missouri and their willingness to comply, supervisory staff's familiarity with the geography of the state which makes them capable of arranging efficient dosimeter placement travel agendas, a network of experienced (and trained) interviewers and field personnel in Missouri, and a fully staffed and equipped office (as opposed to a temporarily site-office) to coordinate activities and process completed work on site.

By choosing SRA to continue this project, the funding agency will:

- have eliminated the time and costs for transition activities;
- continue to benefit from the current cooperative working relationship with the Missouri Cancer Registry and the statewide network of hospitals;
- continue to realize the consistent maintenance of high completion rates in all project activities;
- insure standardization of data collection and quality control efforts for both contracts; and
- receive continued timely delivery of quality data.

b. Trainings

Due to the increased number of case and control identification for this new contract, SRA will train an additional three interviewers for screening and telephone interviewing and ten additional field clerks for completing construction survey and field activities in order to complete the study in the time required. These thirteen field staff would augment the interviewers already trained and working on the project.

SRA's construction expert, Steve Lipkind, Partner and Chief Executive Officer of Joseph Bastian & Co. construction company, trained our current field clerks and monitors the quality of the construction survey. Mr. Lipkind will also assist in the training of the new field clerks. Since all training materials are already developed, the additional costs for training new clerks will be minimal. A copy of Mr. Lipkind's curriculum vitae can be found in Appendix A.

3. Identification of Study Subjects (Cases and Controls)

This section of the proposal discusses identification of cases and controls and screening them for study eligibility. This work flow is depicted in EXHIBIT B.6.

a. Identification of Cases

A case is defined as a white woman residing in the state of Missouri for at least six months who has not smoked for fifteen years or longer, who has been diagnosed as having lung cancer, and is between the ages of 30 and 84. These cases are identified using the reporting system developed by the Missouri Cancer Registry. The SRA Tumor Registry Coordinator, as described in Section B.1, will identify cases in a timely manner by abstracting hospital records sent to this

registry and/or during circuit trips. Patients diagnosed with lung cancer, who have never smoked or who are not current smokers, or whose smoking history is unknown are abstracted by the Tumor Registry Coordinator. SRA will interview cases within 20 days of referral from the cancer registry. If an interview cannot be completed by the case herself, a next of kin interview can be completed with the designated proxy. To date, SRA has completed 93 percent of all cases interviews within this 20-day window.

Once a case is identified by the Tumor Registry Coordinator, a letter is mailed to the physician for consent and she then mails a copy of the physician letter and referral form to the SRA Study Manager, providing the following appropriate information:

- Full name of subject;
- Complete mailing address;
- Telephone number, if known;
- Next of kin, if known;
- Physician;
- Hospital of diagnosis;
- Stage and type of cancer;
- Data of diagnosis; and
- Date of birth.

b. Identification of Controls

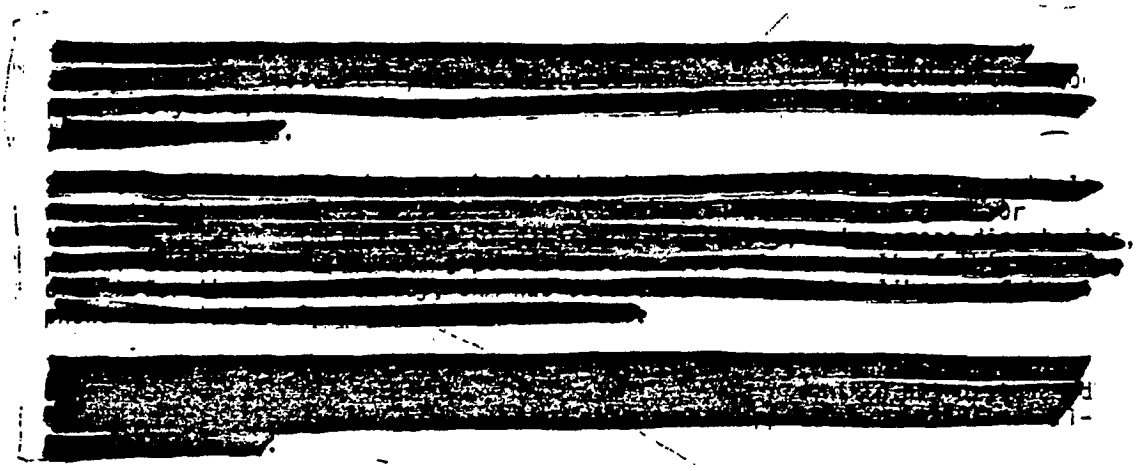
Controls are identified using two methods. For cases aged 30-64, names are randomly generated from lists provided by the Missouri Department of Motor Vehicles (DMV). For cases aged 65-84, names are randomly generated from tapes provided by the Health Care Financing Administration (HCFA).

Dr. Brownson has made the arrangement each year for the tapes from the Missouri DMV. The DMV tape was randomly sampled to provide quota sampling in two age groups, 30 to 54 and 55 to 64. Dr. Alavanja has made the arrangement each year for the tapes from HCFA. The HCFA tape was randomly sampled to provide quota sampling in two age groups, 65 to 74 and 75 to 84. These tapes are sorted in birthdate order and cleaned, removing duplicates and non-resident names and assigning control numbers. Alphabetical and numerical lists are printed for office reference and labels are generated for interviewer use.

Each month the quota of controls needed in each age group are sent appropriate introductory letters explaining the study and, if necessary, asking them to call our toll-free 800-number. Controls whose letter are returned as undeliverable by the postal system are traced and reissued new letters.

c. Generate Telephone Numbers

The telephone number for case subjects or their next of kin is generally available from the abstract information. When the abstract does not have a telephone number or if the number is incorrect, it can generally be obtained by calling the hospital or physician's office. When needed, extensive tracing and locating techniques are implemented to obtain case telephone numbers. All case telephone numbers are eventually obtained. It is anticipated, however, that more tracing may be needed to obtain current telephone numbers for the next of kin of the retrospective cases from 1986 and 1987.



Through the combination of the tracing effort and the response to this letter, SRA has been able to obtain the telephone numbers of an additional 34 percent of sampled controls. Between the response to the 800-number, tracing, and numbers provided by Telematch, SRA was able to identify 89 percent of the telephone numbers for approximately 1,100 sampled control names.

d. Send Introductory Letter (EXHIBIT B.7)

All eligible cases (or their families) and control subjects are sent letters of introduction. These letters explain the purpose of the study and encourage the subjects and their families to take part. A special letter is sent to subjects whose telephone numbers have not been located, asking them to contact the study manager on the toll-free number.

e. Screening for Eligibility

Screening for eligibility is a crucial component of this study and is required for both cases and controls. Each case referred by the Tumor Registry Coordinator must be screened for eligibility in that medical records do not always provide complete and accurate data. To avoid excluding cases that might be eligible, the Tumor Registry Coordinator has been instructed to refer any recently diagnosed cases who might be eligible. In the current study, 60% of the cases referred have not been eligible. The most common reason for ineligibility is that the respondent's smoking history has been recorded incorrectly or has been excluded from the medical records. However, SRA has been able to screen 453 (99%) of the 458 cases referred to date to determine eligibility.

A high completion rate is difficult to achieve among controls since they have no stake in study results. Nevertheless, SRA was able to screen 92 percent of the control population for whom we had identified telephone numbers, for a total of 975 people. Using a combination of Telematch tracing and the 800-number, this effort has been inexpensive and successful. Of those screened, only 59 percent, or 524 persons were eligible.

The eligibility criteria for controls is essentially the same as cases. Controls must be white females between the ages of 30 and 84, residing in the State of Missouri for at least six months, who have not smoked in the past fifteen years (see EXHIBIT B.8 for the study screener). Only 90 possible controls (8 percent) contacted to date have refused to be screened.

EXHIBIT B.7

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

6325 Security Boulevard
Baltimore, MD 21207

The Health Care Financing Administration (HCFA) administers the Medicare program. HCFA is cooperating with the Missouri Health Department and the U.S. Public Health Service on studies which involve Medicare beneficiaries as well as others. These studies will help us learn more about lung cancer, one of the most common cancers in women. People who have been diagnosed with this cancer, as well as people who do not have this cancer, will be included in these studies.

You are one of over 30 million Americans with health insurance under the Medicare program. Your name was selected at random. In a few weeks, you will be contacted by a representative of the research team. That person will want to ask you questions about your health history, diet, smoking habits, pregnancies, and other lifestyle factors.

You do not have to participate in the survey. There are no penalties if you do not want to answer a particular question. Your Medicare benefits will not change based on whether you decide to participate. All answers you give will be kept confidential to the greatest extent permitted by law. If you decide to participate, the information you provide will be combined with that provided by other persons who participate. The research team is trying to obtain a representation of the female population in the state of Missouri.

Very soon, one of the interviewers will call you to find out if you will participate. If so, they will arrange to interview you by phone at a time convenient to you. Meanwhile, if you have any questions about the study, please feel free to call Dr. Michael Alavanja or one of his research associates, toll free, at 1-800-444-5234.

Thank you for your participation.

Sincerely,

William L. Roper

William L. Roper, M.D.
Administrator

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EXHIBIT B.8

MISSOURI WOMEN'S HEALTH STUDY

SCREENER

ID#: |__|-|__|-|__|-|__|-|__|-|__|__|__|| 1

INTERVIEWER #: |__|__|| 8

DATE OF INTERVIEW: |__|__| |__|__| |__|__| 11

BEGIN TIME: |__|__| : |__|__| 17

EDITOR: |__|__| 21

INTRODUCTION TO THE TELEPHONE INTERVIEW ONCE R ON THE PHONE

Hello, my name is _____ and I'm calling for the Missouri Department of Health and the United States Public Health Service. We are conducting a Women's Health Study in the state of Missouri. Recently you were sent a letter explaining the study and letting you know that I would be calling you. Did you receive the letter?

FOR CASES: As stated in the letter, you have been selected scientifically from the Missouri Cancer Registry which includes women like yourself who have been diagnosed with lung cancer during the past year. In order to help researchers better understand possible causes for this disease we would like to complete an interview with you on the telephone.

FOR CONTROLS: As stated in the letter, you have been selected randomly as a resident of Missouri in order to help researchers learn more about women's health in Missouri.

IF CASE DECEASED: Because (NAME) was selected by a scientific method, we would still like to complete the interview with the person who would be most knowledgeable about (NAME's) health and family history. Who would this person be?

IF PERSON ON THE PHONE IS NOT MOST INFORMED PERSON, OBTAIN NAME OF PROXY AND PHONE NUMBER.

IF PERSON ON THE PHONE IS PROXY, CONTINUE:

The Missouri Department of Health, in conjunction with the United States Public Health Service is conducting a Women's Health Study in the state of Missouri. (NAME) was selected scientifically from among women in the Missouri Cancer Registry who were diagnosed with lung cancer. As the person who is most knowledgeable about (NAME), we would appreciate your helping us with this project.

FOR EVERYONE: Your participation is voluntary and all information provided will be kept in complete confidence to protect your privacy. The results of the study will be reported about groups of women and no individuals will be identified. First, I need to ask just a few questions to see if (you are/NAME is/NAME was) eligible to participate in the study.

2025792035

SECTION A - DEMOGRAPHIC INFORMATION

First I need to ask a few general background questions.

A1. What is (your/her) date of birth? |_|_| |_|_| |_|_|_|_| 23
MO DAY YEAR

A2. What is (your/her) current age? |_|_|_| 31
AGE

INELIGIBLE, IF 29 OR LESS, OR 85 OR MORE, STOP AFTER A9. CODE 2 FOR SCREENING DISPOSITION.

A3. In what state or foreign country (were you/was she) born? _____ |_|_|_|_| 34
OFFICE

A4. (Have you lived/did she live) in the state of Missouri for 6 months or longer during (your/her) lifetime?

YES 1 37
NO (INELIGIBLE, STOP AFTER A9. CODE 3 FOR SCREENING DISP) . 2

A5. (Are you/was she) currently married, widowed, separated, divorced or (have you/was she) ever married?

Married 1 38
Widowed 2
Separated 3
Divorced 4
Never Married 5
RF 7

A6. (Do you/Did she/Does she) consider (yourself/herself) (READ CATEGORIES)?

SPECIFY: _____

White, not Hispanic 01 39
White, Hispanic 02
Black, not Hispanic 03
Black, Hispanic 04
Asian or Pacific Islander 05
American Indian or Alaskan native 06
Other . . . . . (SPECIFY) 07
RF 97

|_|_| 41

A7. (Have you/did she) ever use (d) any tobacco products? This includes cigarettes, cigars, pipes.

If R EVER SMOKED 5 PKS OF CIGARETTES (100), CODE YES.

YES . . . . . (GO TO A7.1). 1 43
NO . . . . . .(SKIP TO A8). 2

2025792036

ID#: |__|-|__|-|__|__|-|__|-|__|__|__|

DECK 28

CHANGES TO TELEPHONE SCREENER

RADON STUDY

A7.1 Have you smoked a total of 100 cigarettes in your lifetime?

YES 1 25
NO . . . . . .(GO TO A8) 2

A7.2 Have you ever smoked cigarettes <u>regularly</u> for one year or longer?

YES 1 26
NO . . . . . .(GO TO A8) 2

A7.3 At what <u>age</u> did you start smoking cigarettes regularly?

|__|__|__| 27
AGE

A7.4 Do you smoke regularly now?

YES(INELIGIBLE/GO TO A8-STOP AFTER A8-CODE 5 FOR SCREEN DISP) 1 29
NO 2

A7.5 At what <u>age</u> did you stop smoking cigarettes regularly?

|__|__|__| 30
AGE

SUBTRACT ANSWER A7.5 FROM PRESENT AGE:

- IF 15 YEARS OR MORE, CIRCLE 1 AND <u>CONTINUE</u> 1
- IF LESS THAN 15 YEARS, CIRCLE 2 INELIGIBLE *<u>GO TO A8</u>, STOP AFTER A9; CODE 5 FOR* SCREENING DISP 2

32

A7.6 Thinking about the years between the time you started smoking and stopped smoking, was there ever a period of one year or more that you did <u>not</u> smoke cigarettes?

YES 1 33
NO . . . . . .(GO TO A7.8). 2

A7.7 For how many <u>years</u> did you <u>not</u> smoke cigarettes?

|__|__| 34
YEARS

A7.8 (During periods when you smoked), how many cigarettes did you usually smoke per day?

(1 Pack = 20 Cigarettes)

|__|__|__|__| 36
OF CIGS PER DAY

2025792037

A7.9 (During periods when you smoked), did you usually smoke filter or non-filter cigarettes?

FILTER 1 38
NON-FILTER 2
BOTH 3

A7.10 When smoking cigarettes, did you usually inhale into the chest?

YES 1 40
NO 2

A7.11 In addition to cigarettes, did you use any of the following tobacco products on a regular basis for six months or longer?

	YES [Ask A]	NO (Next Option)	For how long did you use (Option) ?	
A. Pipe	1	2	|__|__|	41
B. Cigars	1	2	|__|__|	44
C. Cigarillos	1	2	|__|__| YEARS	47

OFFICE \|__\|__\|__\|.\|__\| YEARS 50

END 28

2025792038

A8. *What is the highest grade or level of schooling (you/she) completed?*

No Formal Schooling	00	44
1st Grade	01	
2nd Grade	02	
3rd Grade	03	
4th Grade	04	
5th Grade	05	
6th Grade	06	
7th Grade	07	
8th Grade	08	
9th Grade	09	
10th Grade	10	
11th Grade	11	
12th Grade	12	
1 Year College	13	
2 Years College	14	
3 Years College	15	
4 Years College	16	
5 Years College	17	
6 Years College	18	

TRAINING OTHER THAN:

College	19
Other. . (SPECIFY)	96
RF	97

SPECIFY: _____

A9. (Do you/Does she/Did she) have a current Missouri Driver's License?

YES	1	46
NO	2	

CONTINUE TO CODE BOOKLET IF:

- Q.A2 = 30-84 YEARS OF AGE
- Q.A4 = YES, RESIDENT OF MISSOURI FOR 6 MONTHS OR MORE
- Q.A6 = 1 OR 2 - R IS WHITE
- Q.A7 = 2 - R HAS NEVER SMOKED

IF ANY OF THE ABOVE CRITERIA ARE NOT MET, READ:

Thank you very much, that's all the questions I have at this time.

2025792039

4. Data Collection

a. The Field Office

Survey Research Associates, Inc. will continue to manage the Case/Control Study, Residential Exposure to Radon and Lung Cancer Among Non-smoking Women in Missouri from its permanent site office in St. Louis, Missouri, placing the supervisory and field staff in close proximity to the Missouri Cancer Registry and a large population center for the state. SRA has operated this site office in St. Louis since February, 1982 for the purpose of collecting data for research projects conducted for academic institutions, federal agencies, private foundations, and private companies. SRA/St. Louis conducts epidemiological and sociological studies in metropolitan St. Louis, throughout the state of Missouri, and nationwide. Local and national field staff, site office procedures, and quality control procedures have been in place for almost eight years, and are being implemented for the current Case/Control Study, Residential Exposure to Radon.

Patsy Henderson has held the position of Director of Mid-West Operations since its inception in 1982. Other key personnel, such as the Field Director, Data Manager/Quality Control Director, editor/coders, and data entry personnel have also worked in the St. Louis office since it was established. In addition to the St. Louis staff members' experience with SRA, the core personnel of this office each have more than 20 years of experience working on other data collection projects in the State of Missouri. The Director of Mid-West Operations and Field Directors have established networks of contacts throughout all of Missouri including concentrations in the eastern Missouri communities surrounding St. Louis, the western part of the state surrounding Kansas City, the central portion of the state around Jefferson City and Columbia.

Past studies have enabled the St. Louis office staff to become familiar with personnel and record keeping methods in Missouri health care and hospital facilities. During the Epidemiological Catchment Area Mental Health Study (ECA) which SRA/St. Louis conducted for Washington University (NIMH funding), many Missouri hospitals and clinics were contacted, convinced to participate in the study, and frequently visited by SRA data collectors. SRA/St. Louis staff also worked with Missouri hospitals and health care facilities during the Evaluation Study of Programs to Consolidate Services for High Risk Young People (Robert Wood Johnson Foundation funding) and the Breast Cancer Case/Control Interview Project (NCI funding).

During the development of the sampling scheme for the Health Effects of Environmental Hazards study conducted for Washington University (NIMH funding), Ms. Henderson worked with federal, state and local agencies to identify Missouri populations with possible exposure to environmental hazards, including dioxin contamination, well water contaminated by radioactive waste, tornados and flooding. Among the many agencies contacted by Ms. Henderson were the Centers for Disease Control, the Department of Natural Resources, emergency relief agencies, mayors' offices and the governor's office.

For the current Case/Control Study of Residential Exposure to Radon in Missouri, SRA's technical staff in St. Louis has gained much expertise and statewide knowledge concerning hospital record rooms, landlords and apartment management groups, and the peculiarities of conducting field surveys in various unique and remote rural areas.

b. Conduct Trainings

There are several types of trainings that are required to prepare field staff for the activities necessary for this project. Trainings include abstractor training of the Tumor Registry Coordinator; interviewer training for screening and telephone interviewing of cases and controls; and field clerk training for construction assessment, the nutrition questionnaire administration and dosimeter placement; training of editors and coders to carry out specific quality control procedures, and training of data entry technicians and clerical staff. SRA currently has 25 trained staff members performing these activities. For the scope of work outlined for this proposal, however, SRA will require three additional telephone interviewers and ten additional field clerks. Trainings for all six categories of personnel are described below.

(1) Training Manuals and Protocols

SRA developed procedural manuals to train both registry and SRA personnel for the current study. The instructional manuals included manuals for case ascertainment and abstraction, selection and screening of cases and controls, administration of the telephone interview, field placement of dosimeters, field data collection and visual surveying of residences, and coding and quality control procedures.

These manuals thoroughly explain all study procedures and protocols. Each manual contains sections explaining the background and objectives of the study, a step-by-step outline of all procedures to be followed in accomplishing the tasks addressed by that activity, a copy of each form to be used executing that activity, item-by-item specifications for each form or questionnaire, procedures for handling unusual situations which may arise (e.g., refusal conversion in an interviewing manual), and SRA administrative procedures (e.g., time sheets, long distance call records). The training manuals are kept by each trainee for reference throughout the course of the study.

(2) Tumor Registry Coordinator (Abstractor) Training

In the unlikely event that a new Tumor Registry Coordinator (liaison) would have to be trained during the course of the proposed study, the new liaison would be trained by the current liaison and the Study Manager. One of the key factors in the success of this position is maintaining the cooperation and commitment between SRA and the statewide registry staff as well as continuing the efficient referral of identified cases to the SRA office.

In addition to training on inter-agency coordination, abstractor training for the Case/Control Study of Residential Exposure to Radon covers procedures to be followed in the abstraction/ascertainment process, case eligibility determination, item-by-item specifications of the abstract forms, and procedures for referral of cases to SRA. A new liaison would also be advised on how to handle logistical problems such as the wrong files being pulled, not enough space to abstract, and records with contents out of order. Common problem areas such as missing data, illegible data and missing records or parts of records will be reviewed and the liaison will be given rules to follow when these situations occur. A thorough review is provided on medical terminology and abbreviations pertinent to the study, and on the various types of numbering and coding systems that the abstractor is likely to encounter.

In addition to training the liaison on the first phase of the Radon study, SRA has trained abstractors for numerous other studies including the Chronic Renal Failure Study, the Evaluation Study of Services for High Risk Young People, the St. Louis and Eastern Baltimore ECA Mental Health Studies, the Teenage Contraception Study; the Study of Compliance to Medication in Medical Clinics, the Case/Control Study of Prenatal and Neonatal Factors in Childhood Strabismus, and the Dalkon Shield Litigation Project.

(3) Training of Screening/Telephone Interviewers

For this second phase of the study, it is estimated that approximately three new interviewers will have to be trained to complete the work on schedule. These interviewers will be given the same training the current interviewers received. Any persons without prior data collection experience will be trained on basic data collection techniques first. These training sessions emphasize the need for accuracy and attention to detail, as well as the necessity for legible and complete recording of data. New interviewers are taught how to probe vague responses without leading the respondent, and the importance of asking questions exactly as worded and in the order in which they occur.

The formal training session will be conducted in St. Louis by the Project Director, the Field Director and other technical staff. The overall purpose of the training will be to standardize data collection. To that end, it will have several important objectives including:

- instructing on study protocol for screening and interviewing cases, controls, and next of kin;
- instructing on item-by-item questionnaire specifications;
- practicing administration of the questionnaire; and
- discussing respondent profiles and anticipated reactions.

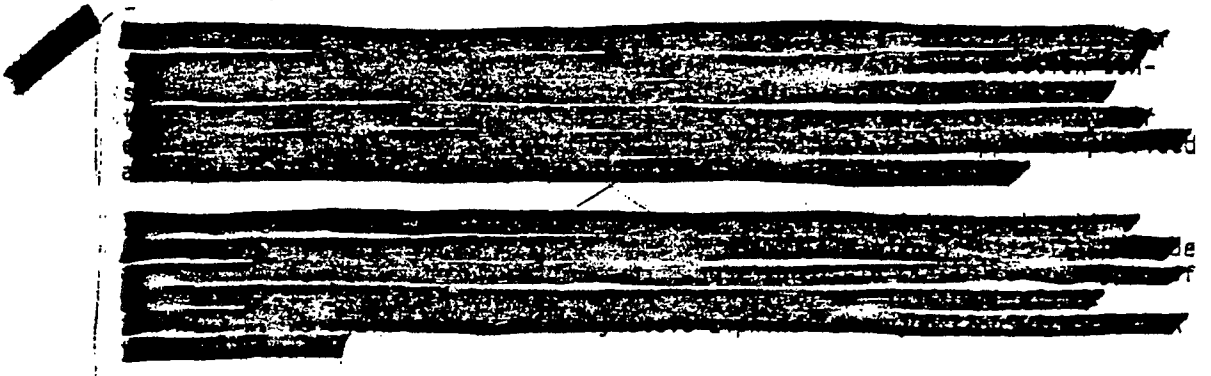
[redacted]

Interviews with cases must be completed within 20 days of physician consent. Timely interviewing of cases subsequent to their ascertainment will be SRA's priority during the telephone interviewing component of data collection. During interviewer training, special emphasis will be placed on techniques for rapid contact with cases and completion of the interview.

(4) Training of Radon Field Clerks

It is anticipated that approximately ten additional field clerks will be needed to complete the statewide field work in a timely and efficient manner. Because residences have been less concentrated in urban areas than initially suspected, a large field staff scattered throughout the State of Missouri is necessary to reduce the time and travel expenses in the placement of dosimeters.

Field clerks will be required to complete formal training conducted by the SRA Project Director, the Field Director and the technical staff. This training focuses on administration of the Household Construction Survey, techniques for obtaining the cooperation of respondents, procedures for Radon dosimeter placement, priority ranking of completing field cases, and the administration of the nutrition questionnaire.



SRA's past experience in contacting households and placing dosimeters will be utilized in training these new field clerks. They will be trained to address various concerns posed by dosimeter placement, such as fear that homes selected for the study are unsafe, fear that the dosimeter itself is a health hazard, or fear of possible consequences if the reading is high. The field clerk will also be advised of how to handle common landlord/tenant situations or how to place dosimeters in residences that do not conform to our "living room/bedroom" ideal.

Since the protocols regarding dosimeter placement have been most varied, SRA's field clerks will have the definite advantage of being trained on actual situations that have occurred to date and are likely to occur again.

(5) Training of Coders/Editors

Coders and editors have already been trained for the current project, and it is not anticipated that additional training will be needed. These coders and editors attended the liaison, telephone interviewer and/or field clerk trainings, then received additional training which covered the manual and machine editing procedures, use of standard and special coding conventions, and maintenance of editing/coding decision logs.

(6) Training Data Entry Personnel

Data entry for this project requires that the data entry personnel have a full understanding of the project. Data entry personnel assigned to the project are trained by the Data Manager in study requirements. This knowledge is required because each level of data entry generates a new level of fieldwork. For example, case/control information generates households for the field visit which in turn generates a tracking record for individual dosimeters. Understanding all of the data entry processes is essential in order to produce accurate reports, labels and study files.

(7) Training of Clerical Staff

Training of the clerical staff is conducted by the Field Director. The complexities of this project require that clerical personnel be trained on each clerical task and how that task impacts on other segments of the study. Training includes knowledge of all filing, record keeping, and tracking procedures. For example, there are nearly 100 variations of form letters that have been developed for this project. Before mailing an advance letter, the clerk must review the available information and determine the most appropriate letter to send to each case or control and current or former residence, keeping in mind all the possible categories of study subjects and living situations. Training of the clerical staff is essential because of the individualized nature of the study.

All field staff (telephone interviewers and field clerks), coders and editors, data entry technicians, and clerical staff are kept abreast of changes or additions to study protocol or question-by-question specifications by memos and a weekly in-person and/or telephone communication with the Field Director. If these changes are complex enough, the staff is brought together for retrainings. As described in later sections of this proposal, the Field Director or an editor reviews with individual field staff any problem that may be occuring.

c. Conduct Telephone Interview

There are numerous steps involved with conducting the telephone interview with case and control subjects. The primary objective of this task is to interview the 110 rapidly ascertained prospective eligible cases and interview them (or their next of kin) within 20 days of physician consent. Due to the efficient case ascertainment system currently in place, SRA has been able to interview 93 percent of prospective cases within this 20-day period. The completion rate for eligible cases is 100 percent.

Because of this past success, SRA proposes continuing the same system managed by the same personnel. As mentioned previously, we anticipate more difficulty in locating and interviewing the 210 restrospectively ascertained cases identified from the 1986 and 1987 cancer registries, and understand that the 20-day interview period is not relevant for these cases.

In addition to the 320 eligible cases, 840 control respondents need to be screened for eligibility and then interviewed. The sampling procedures have already been discussed, and screening will be described below.

The processes needed to obtain these 1,160 case and control interviews are detailed in the this section. A copy of the telephone interview can be found in Appendix G.

(1) Case Referral

As described, the referral of identified cases is made by the Tumor Registry Coordinator to the SRA Field Director by mail immediately upon ascertainment of eligibility.

A case referral form (EXHIBIT B.9) is used by the SRA Tumor Registry Coordinator that contains all pertinent information required to mail an advance letter to the subject, as well as to contact her by phone in order to complete an interview. Information provided on the referral form includes:

- Full name of subject, including maiden name;
- Complete mailing address;
- Telephone number;
- Next of kin;
- Physician of record;
- Hospital of diagnosis; and
- Stage and type of lung cancer.

Subsequent to referral to SRA, the Tumor Registry Coordinator field edits the abstract form for completeness and accuracy and mails it to the Field Director.

(2) Physician Consent

When a case is identified from the Cancer Registry, a letter is sent to the patient's physician informing him or her of the case's identification for the study and requests that he notify the Missouri Department of Health if he has any objections to our contacting the patient. SRA must wait 14 days from the date the physician letter is mailed to allow time for a refusal before the patient is contacted. To date, we have contacted physicians concerning 483 patients and have only received 5 refusals.

(3) Advance Letter for Cases

After waiting the appropriate number of days, the Field Director mails an advance letter explaining the study to each case. In order to maximize the length of field time available for completion of the telephone interview with a case, the advance letter is mailed from a post office whenever possible. Experience has shown that approximately 4 business days must be allowed between the date of mailing and the contact of the subject for interviewing.

When the advance letter is mailed, the target completion date is indicated on the phone interviewer's assignment sheet. The referral form is then filed in the group eligible for telephone interviews.

(4) Screening of Cases

Cases must be screened to determine if they meet the eligibility criteria for the project. To be eligible, cases must be white women, between the ages of 30-84, live in Missouri for at least six months, and either never have smoked cigarettes or not have smoked cigarettes during the last 15 years.

EXHIBIT B.9

THE MISSOURI WOMEN'S HEALTH STUDY
CANCER REGISTRY REFERRAL FORM

ID # |__|-|__|-|__|__|-|__|-|__|__|__|

DATE REF: |__|__| MO |__|__| DAY |__|__| YR

DR LETTER MAILED |__|__| MO |__|__| DAY |__|__| YR R LETTER MAILED: |__|__| MO |__|__| DAY |__|__| YR

PATIENT:

NAME _____ Last _____ First _____ Maiden

ADDRESS _____

_____

COUNTY _____ |__|__|__|

PHONE (H) _____ (W) _____

DOB: |__|__| MO |__|__| DAY |__|__| YR

NEXT OF KIN:

NAME _____ Last _____ First

ADDRESS _____

_____

PHONE (H) _____ (W) _____

RELATION TO PATIENT _____

PHYSICIAN OF RECORD:

NAME _____

PHONE _____

HOSPITAL _____ |__|__|__|

DATE OF DIAGNOSIS |__|__| MO |__|__| DAY |__|__| YR

PRIMARY SITE OF CANCER _____ |__|__|__|__|

STAGE AT ADMISSION:

NONE.....00
IN-SITU.....01
LOCALIZED.....02
REGIONAL, DIRECT EXTENSION.....03
REGIONAL NODES.....04
REGIONAL, DIRECT EXTENSION AND NODES.....05
DISTANT METASTASES.....06
WIDELY DISSEMINATED.....07

HISTOLOGY |__|__|__|__|__|

NOTES: _____

	DATE ASSIGNED	INTRVWR #	DATE RETURNED	RESULT	COMMENTS
1.					
2.					
3.					
4.					
5.					

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(5) Screening of Controls

After the telephone numbers are located for the random sample of controls, SRA telephone interviewers begin the eligibility screening process. During screening, SRA interviewers verify the control's name, age, sex, race, and address and determine whether the control has ever smoked, or smoked in the last 15 years.

SRA asks for the control when calling, but if the control is not available the screener may be completed by any knowledgeable adult household member. If the control is eligible, the informant will be advised that the control will be contacted again at a later date. No proxy interviews are done for control subjects.

For the current study, SRA has been able to screen 97 percent of all sampled control names for which a telephone number was obtained. A large percentage of sampled control respondents (41 percent) are ineligible.

(6) Advance Letter for Controls

For the current study, a monthly quota of controls, grouped by age, was established on the projected number of cases likely to be referred each year. It is anticipated that this same system will be used for the proposed study, as it has proven to be much more efficient than a one-to-one case/control match. For this selected sample, advance letters are sent to those with traced phone numbers. These letters are tailored specifically to explain the importance of the study and to encourage their participation.

A similar letter is sent to those controls without traced telephone numbers requesting the recipient call our 800-number. As mentioned previously, these techniques produced a 97 percent screening rate.

After allowing at least four business days to pass from the time that the advance letters are mailed, the controls are called to be screened and interviewed.

(7) Telephone Interviewing

The SRA Field Director will be responsible for assigning study subjects for telephone interviewing in a timely manner. The telephone interview, which now averages 50 minutes, will be conducted by the St. Louis-based interviewers. The total interviewer time per case to locate, screen, and interview cases and controls is 2.25 hours per case. Because of the age of some of the respondents and the complex family history taken, interviewers often have to recontact subjects at a later date who need time to research complete family history information. The time for this effort is also included in the hours per case.

The interviewers will contact subjects, ascertain the receipt of the advance letter, and request permission to conduct the interview. The interviewer will verify eligibility status for both cases and controls. If the subject agrees to be interviewed, the interviewer will attempt to complete the interview at that time, or may schedule a time that is more convenient for the respondent. If the subject declines, the interviewer will return the case to the office for future refusal conversion. To date, there has been minimal difficulty in getting cases or controls to complete the interview as can be demonstrated by the 100 percent

completion rate for eligible cases and 86 percent completion rate among eligible controls.

It is important to note that since case referral is made soon after the diagnosis, the subject may not be in the best frame of mind to complete the interview. In addition, it is also possible that she will be scheduled for chemotherapy or radiation treatment. These treatments may cause her to want to delay the completion of the interview. Interviewers have had to be very sensitive to these personal difficulties while trying to conduct an interview within stringent time constraints.

Cases identified in the late stages of their illness or who were not referred in a timely manner are frequently deceased by the time that the interviewer contacts the household. Deceased cases accounted for 28% of the eligible cases in the current sample. In the event that the case is either deceased or very ill, every effort will be made to administer a proxy questionnaire to the next of kin within the 20-day time period.

Interviews with proxies can be very difficult because the questionnaire inquires about family members and the cause, date and place of death of the case. Because the case is frequently recently deceased, proxy respondents have to be treated with great sensitivity.

At the end of the telephone interview, the respondent is informed about the home visit, and dosimeter placement.

d. Coding Abstracted Records

The Tumor Registry Coordinator is responsible for coding the abstract as she fills this form out. The currenty Tumor Registry Coordinator is trained in medical record terminology, is certified for tumor registry work, and has had six years of experience in this field. In addition, she has been trained specifically for this study.

In order to obtain the information required on the abstract, she codes from hospital and other health care records provided by these sources through the Missouri Cancer Registry. Missing data is retrieved by telephone from other sources, such as private doctors or pathology reports, or while making the circuit trips.

The Tumor Registry Coordinator's abstracts are manually edited and reviewed upon receipt in the St. Louis office. In addition, 5 percent of the coding is verified for accuracy.

e. Identification of Households for Field Visits

During the administration of the telephone interview, each respondent is asked to provide information not only about her current household, but all of the households in which she has lived for at least a year during the last 30 years, for a maximum of 6 households. Each of the households reported, in the state of Missouri or within 50 miles outside of the border, is then eligible for a field visit. When the completed questionnaires are logged-in by the clerical staff, a list of households, reported by the respondent, is created in order to obtain a complete listing of all households eligible for a field visit. (See EXHIBIT B.10)

Date of Interview:

␣␣-␣␣-␣␣␣-␣␣-␣␣␣␣

AGREED	DAY PREF.	TIME PREF.	DATE ASSIGNED TO CLERK	CLERK # ASSIGNED	COMP. DATE AND DISP.	RET. DATE

Telephone Respondent: _____

Phone ( ) _____

1. Current Address _____
Street

_____
City State Zip

NOTES:

Advance letter sent: _____
Date Init

Rental: yes____ no____

Landlord: _____

_____
Street

_____
City State Zip
Phone ( ) _____

Landlord letter sent: _____
Date Init

EXHIBIT B.10

2. Address _____
Street

_____
City State Zip

Advance ltr. sent:

_____
Date Init.

NOTES:

Y=yes N=no DK=don't know Ref=refused DA=didn't ask
AT=anytime M=morning A=afternoon E=evening
WD=weekday WE=weekend NA=not applicable

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	DATE ASSIGNED TO CLERK	CLERK # ASSIGNED	COMP. DATE AND DISP.	RET. DATE
3. Address _____ Street _____ City State Zip Advance letter sent: _____ Date Init. NOTES:				
4. Address _____ Street _____ City State Zip Advance letter sent: _____ Date Init. NOTES:				
5. Address _____ Street _____ City State Zip Advance letter sent: _____ Date Init. NOTES:				
6. Address _____ Street _____ City State Zip Advance letter sent: _____ Date Init. NOTES:				

EXHIBIT B.10

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In the current study, respondents report an average of 3 residences in the past 30 years (current and two previous). Thus, approximately 3,480 (1160 subjects x 3 homes per subject) will be identified for field visits. However, based on the current study, SRA estimates that only 75 percent of these residences can be contacted as 12% percent will be out of state and 13% will not exist (destroyed, no such address, rural area with no address and no directions). This will leave 2,610 residences that can actually be contacted for dosimeter placement and household surveys.

f. The Field Visit

The field visit is perhaps the most complex and difficult part of the current study. Dosimeters, provided by NCI, need to be placed in the current residence of cases and controls, as well as all previous Missouri residences of study subjects in the past 30 years. In addition, while visiting the residence for dosimeter placement, the interviewer needs to complete a structural survey for each residence and ask those respondents or proxies who completed a telephone interview to complete a nutrition and work history questionnaire (SAQ). The structural survey and SAQ each take about 30 minutes to complete.

This flow of work for the field visits is demonstrated in EXHIBIT B.11.

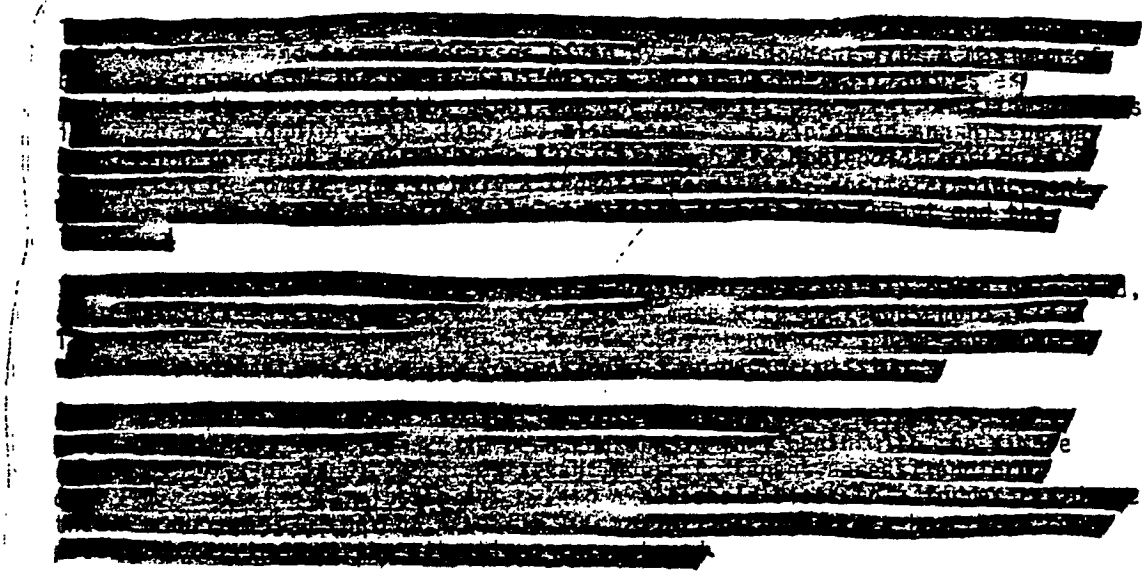
(1) Batching of Assignments

The assignment of field visits requires advance work by the SRA office staff for several reasons. The first is the necessity to prioritize the field visit agenda. This is essential because households are scattered throughout the large state of Missouri. In the early months of the field work it became apparent that the distribution of households would not be as clustered toward the metropolitan areas as originally anticipated through projections obtained from Census Bureau population distribution figures. Actually, of the eligible households identified within the State of Missouri as of October 31, 1989, only 14% were in the Kansas City area, only 33% were in the St. Louis area, and 53% were in other areas of the state. In order to expedite the field visit and contain costs, the method of batching assignments by area was developed using a priority ranking. Each address is given a priority number in the following descending order of immediacy of placement:

1 = current residence of living case
2 = current residence of case interview conducted by proxy
3 = current residence of control
4 = former residences of cases and controls

Using these priority scores in conjunction with geographic areas, interviewer field visit agendas can be coordinated in a more efficient manner. Although every effort is made to be efficient, other criteria also play into the work schedule. For instance, appointments have to be made with each respondent and/or landlord, which is not always compatible with an efficient travel agenda. There are also situations where a respondent is willing to participate but has extensive travel plans or is preparing to move. In these instances, special visits are made so that access to a household is not lost. Because lung cancer case respondents are quite ill and indeed some are deceased, their living arrangements may change soon after diagnosis, requiring timely field visits.

(2) Obtaining Permission



(3) Household Construction Survey

The household construction survey is completed in both current and former residences of study subjects. For administration of the construction survey, the field clerk walks through the house with a household member to inspect the structure; looks for cracks and leaks, determines methods used for heating and cooking in the household; measures the size of the living space; indicates the type of building materials used; determines current ventilation; and records any changes or additions to the structure since it was originally built. The survey takes about 30 minutes to administer with any knowledgeable adult member of the household.

For the current project, 95% of the eligible households have agreed to completing the construction survey. Based on the success of the current project, it is anticipated that, of the 2,610 eligible households for the proposed project in the state of Missouri that are still standing, 2,480 (95%) will complete the construction survey. A copy of the household construction survey can be found in APPENDIX G.

(4) Dosimeter Placement

The present residents of both the current and former residences of study subjects are also asked to allow the field clerk to place Radon dosimeters in their homes. As previously discussed, landlord permission is obtained for all households occupied by renters.

The dosimeters, which are provided by NCI, are track etch detectors and ideally are left in place for a full year before being harvested. Whenever possible, one detector is placed in the kitchen and the second is placed in the master bedroom. The date of the placement, household number and location of the detector is recorded for tracking purposes. Contingency placement protocols have been developed for the multiple configurations of residences, including group quarters such as a dormitory and high rise apartment houses.

EXHIBIT B.12

Missouri Department of
HEALTH

John Ashcroft
Governor

Robert Harmon, M.D.
Director

Dear _____:

The Missouri Department of Health, in cooperation with the United States Public Health Service, is conducting a Women's Health Study in the state of Missouri. The purpose of the study is to learn more about the factors that affect health in the state of Missouri.

Your tenant at _____ will be asked to participate in this study. As part of this project, we would like to send a field technician to the above address. The purpose of this visit is to leave two small (2" in diameter) radon detectors in this residence for one year.

Radon is an odorless and colorless gas which is associated with a small increase in the risk of lung cancer. This visit and placement of the radon detectors is a free service offered by the Missouri Department of Health for those households which are participating in the study.

As landlord, we are requesting your permission to leave these detectors in this household. By participating, you will be helping us to learn more about radon levels in selected homes in the state of Missouri.

Once the detectors have been collected, a copy of the results will be sent to you. As with all information collected for this study, the results of the test will remain confidential.

Your participation in this project is voluntary. Radon detectors will be left only with your permission. Please complete the enclosed reply form and return it in the self-addressed envelope provided.

Your cooperation is greatly appreciated. If you have any questions, please feel free to call Patsy Henderson, Project Coordinator, toll-free, at 1-800-444-5234.

Sincerely,

Dr. Ross Brownson
Project Co-Director
Missouri Department of Health

Michael Alavanja

Dr. Michael Alavanja
Project Co-Director
Public Health Service

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The respondent is instructed to check the detector on a regular basis. A card is left with SRA's detector hotline (800) number in the event that a problem should occur. Respondents in the current study have been extremely conscientious in reporting problems to the SRA office. For example, several households have called to let us know of their intentions to move prior to the retrieval date for harvesting the detector. The study team has developed specific procedures to address the various types of problems that have occurred.

To date, SRA has achieved a 83% completion rate in placing Radon dosimeters in households completing the construction survey. The refusals for placement of dosimeters is currently 6% for households and 11% refusal by landlords. If 2,480 households in the proposed project complete a construction survey, it is projected that dosimeters will be placed in 2,058 households.

(5) Nutrition and Occupation Questionnaire

The final portion of the field visit, the nutrition and work history questionnaire, is completed only in current residences of study subjects. The explanation of the questionnaire and its' administration together require approximately 30 minutes. Initially, this questionnaire was designed to be self administered. However, it was determined, based on the data retrieval required, that the quality of the data obtained would be greatly improved if it was completed with the field clerk during the home visit. Every effort is made to complete this questionnaire at the time of the home visit. A copy of the nutrition and occupation questionnaire can be found in APPENDIX G.

However, if the study subject is not home at the time of the field visit, a copy of the questionnaire is left with another household member. The respondent can then complete the form on her own and an editor from the SRA office will call to review any discrepancies with the respondent or an interviewer will administer the questionnaire to the respondent over the phone.

For the current study, 93% of the study subjects have completed the nutrition and occupation questionnaire.

g. Additional Dosimeter Efforts

(1) Dosimeter Surveillance

For all dosimeters placed by field clerks, routine monitoring for compliance needs to take place. At one-month post-placement, a telephone call is made by the SRA staff to insure that the dosimeters are safe and in place. If the dosimeters are still in place at the time of this call, quarterly reminder postcards are sent to each household. If a dosimeter has been lost, a new dosimeter is mailed to the household with instructions for placement. All of the forms are then changed to indicate the new date for placement and the designated date of retrieval. Lost or damaged dosimeters are replaced as needed. In certain situations, charcoal canister detectors have also been used to obtain a reading for a shorter period of time if necessary. A copy of the Radon detector tracking form is shown as EXHIBIT B.13.

EXHIBIT B.13

RESIDENTIAL EXPOSURE TO RADON

RADON DETECTOR TRACKING FORM

RESIDENCE #:
NAME
ADDRESS

CITY
PHONE: PRIORITY #:

FIELD CLERK #: |__|__|

DATE PLACED: |__|__| |__|__| |__|__|

RETRIEVAL DATE: |__|__| |__|__| |__|__|
MO DAY YR

Current Placement Code |__|__|__|__|__|__|

I. RADON DECTECTOR PLACEMENT

Detector #1: |__|__|__|__|__|__|__|__| Placement: K B O _____

Detector #2: |__|__|__|__|__|__|__|__| Placement: K B O _____

II. ONE MONTH REMINDER CALL

Reminder Date: |__|__| |__|__| |__|__|

Attempts:

INT #	TIME	DATE
1		
2		
3		
4		

Result: Complete.....1
No Phone.....2
No Locate.....3
Other.....(SPECIFY).....4

Notes: _____

Computer Entry: _____

GENERAL NOTES: _____

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EXHIBIT B.13

III. POSTCARD REMINDERS

3 MOS. |_|_|_|_|_|_| MAILED: |_|_|_|_|_|_| INT.: |_|_|

6 MOS. |_|_|_|_|_|_| |_|_|_|_|_|_| |_|_|

9 MOS. |_|_|_|_|_|_| |_|_|_|_|_|_| |_|_|

NOTES: _____

_____

_____

_____

IV. RETRIEVAL

Packet Mailed: |_|_|_|_|_|_| Reminder Calls: |_|_|_|_|_|_| INT: |_|_|

|_|_|_|_|_|_| |_|_|_|_|_|_| |_|_|

|_|_|_|_|_|_| |_|_|_|_|_|_| |_|_|

Packet Received:
By Mail.....1
In Person.....2
Lost.....3
Moved.....4
Unable to Return.....5

Notes: _____

_____

_____

Date Received: _____ Computer Entry: _____

V. ANALYSIS

Packet Mailed: |_|_|_|_|_|_| Batch #: |_|_|

Detector #1: |_|_|_|_|_|_|_| Location: K B O Result: |_|_|_|.|_|

Detector #2: |_|_|_|_|_|_|_| Location: K B O Result: |_|_|_|.|_|

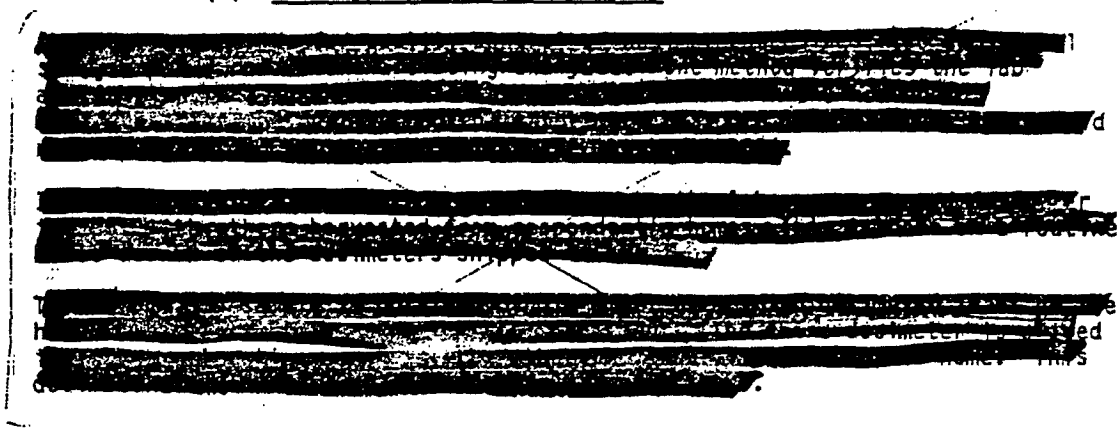
Date Received: _____ Computer Entry: _____

PLACEMENT/RETRIEVAL DISPOSITION

2 TE.....02
1 TE.....03
1 TE/1 CHAR.....07
2 CHAR.....08
1 CHAR.....09
3 TE.....10
2 TE/1 QC.....11
1 TE/1 QC.....12
1 TE/1 CHAR/1 QC.....13
3 TE/1 QC.....14
2 TE/1 WINTER.....15
1 TE/1 WINTER.....16
1 TE/1 CHAR/1 WINTER.....17
2 CHAR/1 WINTER.....18
1 CHAR/1 WINTER.....19
3 TE/1 WINTER.....20
1 WINTER.....21
2 TE/2 WINTER.....22
1 TE/2 WINTER.....23
1 TE/1 CHAR/2 WINTER.....24
2 CHAR/2 WINTER.....25
1 CHAR/2 WINTER.....26
2 WINTER.....27

2025792056

(2) Quality Control of Dosimeters



(3) Harvesting Dosimeters

The harvesting of dosimeters is scheduled to take place one year after the placement. Households eligible for retrieval each month are generated by the computer tracking system. The household is mailed a letter of instructions, seals to place over the dosimeter openings, and a mailer to return the dosimeters to the SRA office (see EXHIBIT B.14). Those households that do not return dosimeters within a few weeks of the due date are contacted to encourage retrieval. If the dosimeters are still not returned, a field clerk is sent to the household to retrieve the dosimeters in person. If one or both of the dosimeters have been lost, the household is asked to place a short-term charcoal canister detector for each one lost.

At this time, 96% of the dosimeters that are time eligible have been harvested for the current project. If 2,058 households in the proposed project each have 2 detectors placed in their homes, a total of 4,116 detectors will be placed. Estimating that 4% will be lost, respondents will have moved or refuse to return the detectors, 3,951 detectors will be harvested for the proposed project. In addition to the 3,951 detectors there will be approximately 206 quality control detectors retrieved for a total of 4,157.

As dosimeter are harvested they are batched and sent to the lab on a regular basis. When the results are returned they are appended to other data collected for the household and the results are sent to the household and/or the landlord.

h. Arrangement for Pathology Review Panel

Three meetings of a pathology review panel will be planned during the contract period. The purpose of the meetings will be for the pathologists to code the cell types in the pathology material of the 600 lung cancer cases in this study. 280 of the cases will be from the first contract and the remainder, 320 will be from the proposed contract.

The first meeting will be planned during Year I of the contract and will code the cell types of cancers from cases for the current contract. The other two meetings will be conducted in Year II with the latter meeting occurring after the identification of all eligible cases for the proposed contract.

2025792057

Missouri Department of
HEALTH

John Ashcroft
Governor

Robert Harmon, M.D.
Director

The radon detectors placed in your home as part of the Missouri Women's Health Study have been in place for one year. We are now ready for them to be returned.

Please follow these instructions when returning the detectors:

1. Place the enclosed gold seals over the holes in the detectors.

2. Write date removed from the room on the strip attached to the detector.

3. Wrap the detectors in the enclosed aluminum foil.

4. Return in the postage paid envelope.

Thank you so much for participating in the Missouri Women's Health Study. Your detector readings will be sent to you after we receive them from the laboratory.

If you have any questions, please call the study supervisor, Joan Huber, or me toll free at 1-800-444-5234.

Sincerely,

Patsy Henderson

Patsy Henderson
Field Director
Missouri Women's Health Study

2025792058

SRA has contacted the Missouri Cancer Registry in relation to the needs of the pathologists in conducting these meetings. We have been assured that the facilities and the equipment required will be available without charge at either the Cancer Registry or the University of Missouri at Columbia.

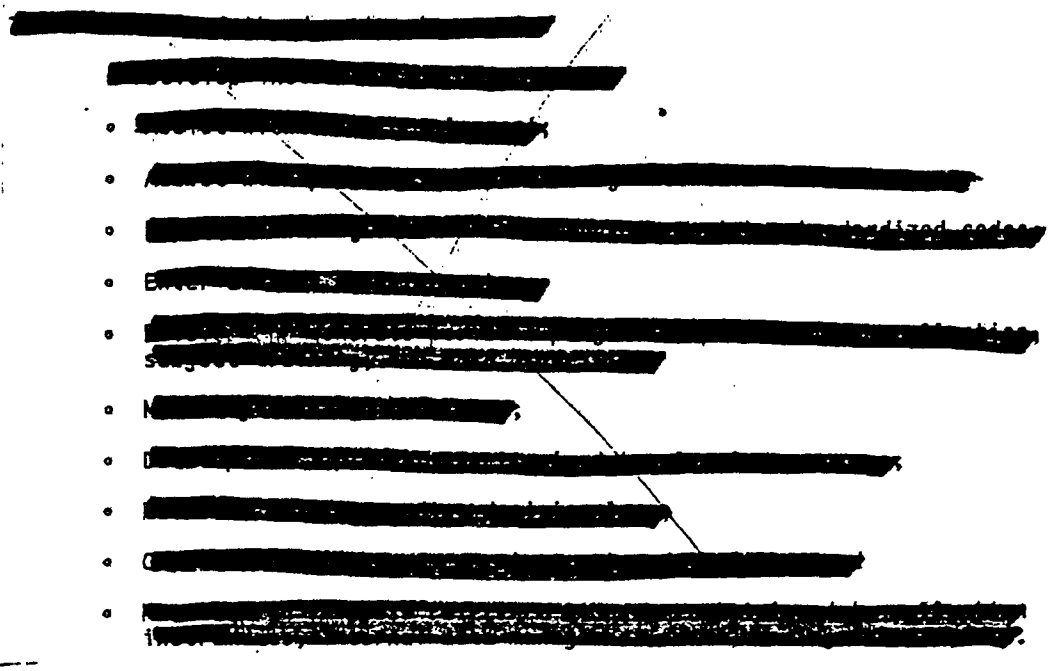
In preparation for the meetings, SRA's Tumor Registry Coordinator, who is located in Columbia, Missouri will collect the slides, pathology reports, medical record abstracts and any other materials required during her circuit riding trips. Her familiarity with the Cancer Registry and hospitals statewide should greatly facilitate this process. Should the Tumor Registry Coordinator require additional assistance, the Study Manager, who is only two hours away from Columbia, will be available to collect the materials in St. Louis or make the necessary trips to Columbia.

The travel and lodging arrangements for the two out-of-state pathologists will be made by SRA's office manager in St. Louis.

An SRA staff member will be available to assist in any way necessary during each of the 4-5 day meetings.

5. Data Preparation And Processing

All phases of data preparation and processing are handled by the Quality Control and Data Processing Departments at the SRA Office in St. Louis. These departments serve as a link between data collection activities and data management activities.



The departments are headed by the Data Manager/Quality Control Director who serves as liaison to the Field Director and programmers. The Data Manager is responsible for the timely and efficient processing of data through implemen-

tation of schedules and priorities set by the Project Officer and the SRA Project Director. The Data Manager/Quality Control Director is responsible for all manual editing and coding processes, the development of the computer cleaning programs and all aspects of the electronic data cleaning process.

Data preparation and processing will be conducted on four sets of data which must be computer-entered into data files: abstract data, telephone interview data, construction survey information, and nutrition and work history data. (Refer to Section 6.a for information on the tracking database.)

a. Edit Telephone Interviews

(1) Editing

All telephone interviews are 100% manually edited for problems such as inconsistencies, miscoded responses, unclear responses and missing data. Editing involves a question-by-question review. Edit problems and errors are recorded on an Edit Form (EXHIBIT B.15) for every interview. To maximize the accuracy of the data, all problems detected are reconciled through consultation with interviewers, retrieval from respondents, or consultation with investigators. Reconciliations are also recorded on the Edit Sheet. SRA's editors who have been working on this project will continue to edit the interviews completed for Phase II.

(2) Coding

The editors are also responsible for coding open-ended questions that are keypunched into the data file. The coding schemes currently being used for the Case/Control Study of Residential Exposure to Radon were developed by the Data Manager/Quality Control Director and approved by the Project Officer. Codes are updated as necessary with approval from the Project Officer. SRA has extensive experience in utilizing a variety of coding schemes, several of which are being used for this study. They include:

- The 1980 Census Occupational and Industry Codes;
- International Classification of Diseases (ICD-9) for morbidity and mortality coding;
- State codes such as Missouri residential codes (cities and counties) and Missouri hospital codes; and
- Internally developed codes specifically designed for variables for which there are no pre-existing codes.

An important part of the editing/coding process is resolution of edit problems. Whenever an editor/coder encounters a problem which cannot be resolved by reference to the question-by-question specifications in the training manual, or through data retrieval or the edit decision log, s/he refers the case to the Data Manager/Quality Control Director. The Data Manager/Quality Control Director, in consultation with the Project Officer, resolves editing/coding problems and records all decisions in the Edit Decision Log (EXHIBIT B.16). This log is then included in the documentation sent to the Project Officer at the end of the study.

2025792060

CHECK ONE: _____ 1ST EDIT EXHIBIT 8.15

_____ 2ND EDIT

EDIT FORM

STUDY: _____ CASE#: _____

INTERVIEWER: _____ I.D.# _____ INT.DT. ___/___/___

EDITOR: _____ I.D.# _____ ED.DT. ___/___/___

COMMENTS: _____

_____

_____

	PAGE	QUES.	CORRECTED BY			EDIT PROBLEM	EXPLANATION
			INT.	ED.	SUP.		
*						1 2 3 4 5 6 7	
*						1 2 3 4 5 6 7	
*						1 2 3 4 5 6 7	
*						1 2 3 4 5 6 7	
*						1 2 3 4 5 6 7	
*						1 2 3 4 5 6 7	
*						1 2 3 4 5 6 7	
*						1 2 3 4 5 6 7	
*						1 2 3 4 5 6 7	
*						1 2 3 4 5 6 7	
*						1 2 3 4 5 6 7	
*						1 2 3 4 5 6 7	
*						1 2 3 4 5 6 7	
*						1 2 3 4 5 6 7	

1. QUESTION SKIPPED BY MISTAKE
2. QUESTION SHOULD HAVE BEEN SKIPPED
3. NEED ADDITIONAL INFORMATION
4. INCONSISTENT DATA
5. INCORRECT CODE OR NO CODE
6. EXTRANEOUS INFORMATION
7. CIRCLE * ASTERISK IF RETRIEVAL IS NECESSARY

2025792061

F0027/MIS/071289

EXHIBIT B.16

EDIT DECISION LOG

STUDY_____

QUESTION #_____

PAGE #	QUESTION #	EDIT DECISION	DECISION DATE	DECISION BY

(3) Validation of Interviews

In an effort to maximize the validity and consistency of the data, 10% of all completed interviews are randomly selected by the Data Manager/Quality Control Director for validation with the respondent. Each respondent selected for validation is called and re-asked selected interview questions. The respondent is also asked to report on the length of the interview and the demeanor of the interviewer. Validations are recorded by the Data Manager/Quality Control Director on the Missouri Women's Health Study Validation Form (EXHIBIT B.17). If applicable, data retrieval is completed at the time of the validation and if the data gathered during validation is inconsistent with data from the original interview, the situation is discussed with the interviewer. If a particular interviewer produces an unacceptable level of inconsistent data, s/he is terminated from the project. To date, all interviewers on the project have validated well.

(4) Second Editing of Interviews

The Data Manager/Quality Control Director monitors the editor/coder's error rate by second editing a random selection of 10% of all edited cases using the Quality Control Evaluation of Editors report (EXHIBIT B.18) and the Cumulative Quality Control Report (EXHIBIT B.19). If there are any errors, the Data Manager/Quality Control Director discusses them with the editor/coder. If the editor/coder has an unacceptable error rate which does not improve to the required standard after retraining, the editor/coder will be terminated from the project. The experienced editors/coders working on this study, have demonstrated excellent capability and will continue to work on this new phase of the work.

(5) Editing Production

Editing production is also monitored by the Data Manager/Quality Control Director through the use of the Daily Production Log (EXHIBIT B.20) and the Quality Assurance Weekly Status Report (EXHIBIT B.21). Production goals are set in terms of editing minutes per interview and carefully monitored by the Data Manager/Quality Control Director through the use of computerized personnel performance records. Editor/coders who are unable to meet production requirements are removed from the study.

(6) Consistency of Telephone Interviewing Editing Procedures with Those Used for the Household Construction Survey

Steps identical to those described in this section thus far are also used to edit the Household Construction Surveys, and the Nutritional and Work History Questionnaire (also referred to as the SAQ).

b. Code Abstracts

(1) Preparation and Processing of Abstract Data

Medical records for cases will be abstracted over a 12-month period by the Tumor Registry Coordinator who is a Certified Tumor Registrar. These forms will be edited by one of the trained, experienced editor/coders on staff at the St. Louis SRA Office. Medical and other information will be coded in computer-readable form on an abstract data collection form used by the Tumor Registry Coordinator from the Missouri Cancer Registry. The editor/coder will

EXHIBIT 8.17

THE MISSOURI WOMEN'S HEALTH STUDY

Radon Telephone

R. Name_____ Case#_____

Address_____ Interviewer_____

_____ Interviewer Date_____

City State Zip

Telephone (____)_____ Sex_____ DOB_____

DATE	TIME	# OF ATTEMPTS	RESULTS AND REMARKS

Hello, I'm_____, a supervisor for the Missouri Women's Health Study in which your participate recently.

I'd like to ask you a few quick questions about your interview, just so we can be sure you had a satisfying experience.

1. What (is/was) the primary source of heat in this residence? (Is/Was) there a back-up or supplemental source of heat?
(IF YES) What (is/was) it?
IF CHANGED DURING RESIDENCE, PROBE FOR MAJORITY OF THE TIME.

SPECIFY: _____

	1° 50	2° 52
NONE	00	
GAS FURNACE	01	01
OIL FURNACE	02	02
HEAT PUMP	03	03
ELECTRIC (BSBRD/OTHER)	04	04
FIREPLACE (OPEN)	05	05
WOOD STOVE	06	06
COAL STOVE	07	07
KEROSENE HEATER	08	08
SOLAR	09	09
OTHER.....(SPECIFY)	10	10
DK	99	99

2. What (is/was) the primary method of cooking or fuel (you/she) (use/used) for cooking in this residence? (Is/Was) there an additional method of cooking? (IF YES) What (is/was) it?
IF CHANGED DURING RESIDENCE, PROBE FOR MAJORITY OF THE TIME.

SPECIFY: _____

	1° 56	2° 58
NONE	00	
NATURAL GAS	01	01
PROPANE GAS (BOTTLED GAS)	02	02
ELECTRIC	03	03
MICROWAVE	04	04
WOOD (STOVE OR FIREPLACE)	05	05
CHARCOAL (GRILL OR STOVE)	06	06
COAL (COAL STOVE)	07	07
OTHER.....(SPECIFY)	08	08
DK	99	99

2025792064

EXHIBIT B.17

3. How tall are you? ___ FT ___ IN

4. What was (your/NAME's) usual occupation, that is, the job (you/she) held for the greatest length of time, during (your/her) adult life? What were (your/her) major duties? For what type of business or industry did (you/she) work?

JOB _____

DUTIES _____

INDUSTRY _____

5. How long did your interview last? Would you say .....
About 30 minutes 1
30-60 minutes 2
60-90 minutes 3
90 minutes or more ... 4

6. Did you feel that the interviewer was very pleasant, somewhat pleasant or not polite at all?

Very Pleasant 1
Somewhat Pleasant 2
Not Pleasant at all ... 3

7. Do you have any other comments that I might pass on to the Study Director?_____

_____

_____

_____

_____

8. ASK DATA RETRIEVAL QUESTIONS AND CODE: NO DATA RETRIEVAL 0
YES, DATA RETRIEVAL 1

Thank you for allowing our interviewer the time to interview you and for speaking to me this morning/afternoon/evening.

2025792065

EXHIBIT B.10

QUALITY CONTROL EVALUATION OF EDITORS

EDITOR'S NAME _____

EDITOR'S NUMBER _____

	Case #	Date of 1st Edit	Date of 2nd Edit	2nd Editor	# of Editor Err	Difficulty of Intvw*
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
16.						
17.						
18.						
19.						
20.						
21.						
22.						
23.						
24.						
25.						

COMMENTS: _____

* E = Easy interview, few formal probes or program use questions, mainly negative responses
M = Moderately difficult interview; positive responses in some sections
D = Difficult interview, many formal probes, many program use questions, many positive responses, and/or respondent could/would not focus on questions, and/or interviewer error made editing difficult.

2025792066

EXHIBIT B.19

CUMULATIVE JALITY CONTROL REPORT

DATE: FROM _____ TO _____

EDITORS	# OF EDITS DONE	# OF EDITS SECOND EDITED	AVERAGE # OF EDITOR ERRORS*	NUMBER OF INTERVIEWS BY CATEGORY OF DIFFICULTY**		
				E	M	D

* AVERAGE # OF EDITOR ERRORS = $\frac{\text{TOTAL OF ERRORS IN "\# OF Editor Err" COLUMN OF QUALITY CONTROL EVALUATION FORM}}{\text{\# OF EDITS SECOND EDITED}}$

** E = Easy interview, few formal probes or program use questions, mainly negative responses.
M = Moderately difficult interview; positive responses in some sections.
D = Difficult interview, many formal probes or many program use questions, many positive responses, and/or respondent could/would not focus on questions and/or interviewer error made editing difficult.)

2025792067

DAY:_____ DATE:____/____/_____

DAILY PRODUCTION LOG

	R A T				R A H				S A Q				S K			
	# HRS	# CASES	EXP.# HRS/C	ACT.# HRS/C	# HRS	# CASES	EXP.# HRS/C	ACT.# HRS/C	# HRS	# CASES	EXP.# HRS/C	ACT.# HRS/C	# HRS	# CASES	EXP.# HRS/C	ACT.# HRS/C
M.BARTHEL			.50				.25				.17				.50	
M.BRISCOE			.50				.25				.17				.50	
L.BRUNS			.50				.25				.17				.50	
J.GREAVES			.50				.25				.17				.50	
J.HALL			.50				.25				.17				.50	
L.KOESTERER			.50				.25				.17				.50	
			.50				.25				.17				.50	
			.50				.25				.17				.50	
			.50				.25				.17				.50	
			.50				.25				.17				.50	
			.50				.25				.17				.50	
			.50				.25				.17				.50	
			.50				.25				.17				.50	
			.50				.25				.17				.50	
TOTAL #																

EXHIBIT B.20

F0028/MIS/120689

20257920G8

QUALITY ASSURANCE

WEEKLY STATUS REPORT

DATE: _____

STATUS OF CASES	HIPS	RADON			AIDS		HOMELESS		SARA	DTLC
	S B D	R A T	H H	S A Q	S M A	S M I	S U M	S U W	SI	SK
COMPLETED CASES										
EDITED CASES										
INCOMPLETE CASES										
UNTOUCHED CASES										
READY FOR KEYPUNCH										
CASES AT KEYPUNCH										
KEYED										
IN CLEANING										
CLEANED										

EXHIBIT B-21

F0046/MIS/111289

2025792069

also be responsible for verifying abstracts by re-abstracting records for approximately 5% of cases. The coder will be supervised by the Data Manager/ Quality Control Director.

For the abstracts obtained during the Case/Control Study, Residential Exposure to Radon, the Data Manager/Quality Control Director, working closely with the NCI Project officer, will develop manual-editing procedures. These procedures will be documented in a Coding/Editing Procedures Manual. This manual will include question-by-question specifications for the abstract form. The general coding of the abstract form will be performed by the Tumor Registry Coordinator using the International Classification of Diseases for Oncology (ICD-O) for disease coding and the SEER Summary Staging Guide for Staging Codes. All abstract coding and editing procedures will be consistent and compatible with those used during Phase I of the study.

The abstracting data collection forms will be manually edited prior to being electronically edited. Any missing or incomplete data will be retrieved by the Tumor Registrar Coordinator. During the manual edit, the editor/coder will read any notes written by the Tumor Registry Coordinator which may qualify an answer or indicate an edit or coding decision is required (e.g., the abstractor may note that a lab report indicated that a particular measurement may be falsely elevated due to a difficulty in specimen processing and the abstractor is unsure whether to record it as abnormal).

(2) Training of Abstract Editor/Coder

SRA uses a proven system for training and supervision of editors/coders and data processing personnel that was developed internally and has been used successfully since 1980. These procedures work extremely well, as evidenced by SRA's one-year contract with Lovelace Medical Center in Albuquerque, New Mexico. SRA provided quality control consultation for that contract, developing and supervising procedures for both the manual and computerized editing of the very complex Diagnostic Interview Schedule (DIS) used in that study. The procedures used on that study have been used on the Missouri Women's Health Study to date and will continue to be used.

The Data Manager/Quality Control Director will verify 100% of the editor/coder's first batch of approximately 10 completed abstracts and will review any errors or other problems with the editor/coder. During this verification procedure, the Data Manager/Quality Control Director will check not only for coding errors but will also ascertain whether the coder is able to recognize responses which should be referred for a coding or editing decision. The editor/coder's ability to recognize coding or editing problems is crucial for high quality data since these types of problems are not usually detected by an electronic edit of the data.

(3) Abstract Coding Procedures

When an abstract is received in the St. Louis Office, its receipt is logged into the computerized tracking database. The abstract is then placed in a file designated for editing/coding. The manual edit and coding process involves a question-by-question review of the data collection form and coding the open-ended items. At this step, the data are checked for inappropriate skipping of questions, double coding, inconsistencies and illegible responses. If a form is found to have errors, the errors are documented on an Edit Sheet (EXHIBIT B.15),

and the form is flagged for data retrieval. SRA usually does data retrieval of information on both abstracts and questionnaires when the information is missing, inconsistent (unless noted by the abstractor that the record was inconsistent), or needs clarification. Data retrieval will be accomplished by the Tumor Registry Coordinator via her telephone calls or circuit riding trips.

(4) Verification of Abstracts

Five percent of the abstracts will be randomly selected by the Data Manager/Quality Control Director for verification. The Data Manager/Quality Control Director will complete a Verification Sheet for each verified abstract. An independent abstract will be completed using copies of the medical records. The two abstract forms will be compared and any discrepancies will be resolved.

c. Keypunch and Verification of Abstracts

Following the editing and coding, abstracts will be computer-entered using verification. Data entry will be done in the St. Louis office on an IBM-compatible microcomputer. SRA uses a database management package which allows verification of data by double-keying and provides error messages when a value does not match. All data entry for this study will be 100% key verified by a second data entry person.

SRA's database management software is interactive and allows ranges and/or individual acceptable values to be defined for a field prior to input (error trapping). Error messages can be written to be displayed when an unacceptable value is keyed. Each field definition can be set up either to display the message and not to allow entry of the data or to display a warning message but allow the data entry person to override the value specification (a feature which is useful in fields where there is a reasonable range but the possibility of a valid answer outside this range). Our program also allows automatic skips when the answer to one question requires skipping to a question other than the next one.

d. Electronic Data Cleaning

The Phase II Telephone Interview, Household Survey, SAQ and Abstract data will be keyed and verified using the same procedures that were used to key and verify these components of the Phase I data. As with the data files of the Phase I components, the Phase II component data files will be prepared in ASCII format and will be analysis-ready upon delivery.

In addition to the interactive data entry system, SRA uses in-house computer editing programs to electronically clean data sets. These programs, which are run on fixed ASCII data files, check the range of values (EXHIBIT B.22) for every item, conduct logics checks for inconsistencies and skip patterns (EXHIBIT B.23), and compare values between fields (EXHIBIT B.24), using computations when necessary (e.g., checking to see that the year of admission to an adult program is at least 18 years greater than the year of birth). Any errors in the data are printed case-by-case in an easy-to-read format (EXHIBIT B.25). Once the corrected information is retrieved by the editor/coder, it is entered into the computer. Documentation of this process is recorded by the data processors and submitted to the Data Manager/Quality Control Director.

EXHIBIT B.22

RANGE OF VALUES FILE = RAT.RV

NO.	CARD	COLUMN	WIDTH	ACCEPTABLE VALUES
1	1	1	1	1 , 2 ,
2	1	2	1	3 - 6 ,
3	1	3	2	0 - 12 ,
4	1	5	1	8 , 9 ,
5	1	6	3	1 - 999 ,
6	1	9	2	26 , 30 , 37 ,
7	1	11	2	1 - 12 ,
8	1	13	2	1 - 31 ,
9	1	15	2	88 , 89 ,
10	1	17	2	8 - 21 ,
11	1	19	2	0 - 59 ,
12	1	21	2	13 , 17 , 19 , 28 , 36 ,
13	1	23	2	1 - 12 ,
14	1	25	2	1 - 31 ,
15	1	27	4	1903 - 1958 ,
16	1	31	3	30 - 85 ,
17	1	34	3	1 - 999 ,
18	1	37	1	1 ,
19	1	38	1	1 - 5 , 7 ,
20	1	39	2	1 - 2 ,
21	1	41	2	BLANK.
22	1	43	1	1 , 2 ,
23	1	44	2	0 - 19 , 96 , 97 ,
24	1	46	1	1 , 2 ,
25	1	47	2	26 , 30 , 37 ,
26	1	49	2	1 - 12 ,
27	1	51	2	1 - 31 ,
28	1	53	2	88 , 89 ,
29	1	55	3	25 - 120 ,
30	1	58	2	13 , 17 , 19 , 28 , 36 ,
31	1	60	2	13 , 17 , 49 , 58 ,
32	1	62	1	BLANK, 1 ,
33	1	63	1	BLANK, 2 ,
34	1	64	1	1 ,
35	1	65	1	1 , 2 ,
36	1	66	1	1 , 2 ,
37	1	67	1	1 , 2 ,
38	1	68	1	1 , 2 ,
39	1	69	1	1 , 2 ,
40	1	70	2	8 - 21 ,
41	1	72	2	0 - 59 ,
42	1	74	1	1 ,
43	1	75	4	BLANK.
44	1	79	2	1 ,
45	2	1	1	1 , 2 ,
46	2	2	1	3 - 6 ,
47	2	3	2	0 - 12 ,
48	2	5	1	8 , 9 ,
49	2	6	3	1 - 999 ,
50	2	9	1	1 - 6 ,
51	2	10	2	BLANK. 1 - 12 ,
52	2	12	2	BLANK. 50 - 88 ,
53	2	14	2	3 - 88 ,
54	2	16	1	1 , 2 ,
55	2	17	1	1 , 2

EXHIBIT B.23

L O G I C S FILE = RATE.LOG

CONDITION	CARD	COL	WIDTH	ACCEPTABLE VALUES
3 IF	1	1	1	1 ,
*** THEN ***	1	3	2	1 - 12 ,
5 IF	1	1	1	2 ,
*** THEN ***	1	3	2	0 ,
7 IF	1	2	1	3 ,
*** THEN ***	1	31	3	30 - 54 ,
9 IF	1	2	1	4 ,
*** THEN ***	1	31	3	55 - 64 ,
11 IF	1	2	1	5 ,
*** THEN ***	1	31	3	65 - 74 ,
13 IF	1	2	1	6 ,
*** THEN ***	1	31	3	75 - 85 ,
15 IF	1	11	2	4 , 6 , 9 , 11 ,
*** THEN ***	1	13	2	1 - 30 ,
17 IF	1	11	2	2 ,
AND IF	1	11	2	88 ,
*** THEN ***	1	13	2	1 - 29 ,
20 IF	1	11	2	2 ,
AND IF	1	11	2	89 ,
*** THEN ***	1	13	2	1 - 28 ,
23 IF	1	23	2	4 , 6 , 9 , 11 ,
*** THEN ***	1	25	2	1 - 30 ,
25 IF	1	23	2	2 ,
*** THEN ***	1	25	2	1 - 28 ,
27 IF	1	43	1	1 ,
*** THEN ***	28	25	1	1 , 2 ,
29 IF	1	43	1	2 ,
*** THEN ***	28	25	54	BLANK ,
31 IF	1	49	2	4 , 6 , 9 , 11 ,
*** THEN ***	1	51	2	1 - 30 ,
33 IF	1	49	2	2 ,
AND IF	1	53	2	88 ,
*** THEN ***	1	51	2	1 - 29 ,
36 IF	1	49	2	2 ,
AND IF	1	53	2	89 ,
*** THEN ***	1	51	2	1 - 28 ,
39 IF	1	64	1	1 ,
*** THEN ***	1	74	1	1 ,

EXHIBIT B.24

VALUE OF COMPARISONS

```
        N,28
        F,1,8
        R,82
   1.   23,49,2,>=,21,74,2,0,+,23,44,2
   2.   22,23,2,<=,1,29,2,+45
   3.   22,23,2,>=,1,29,2,+13
   4.   22,29,2,<=,1,53,2,0,-,22,23,2
   5.   23,66,2,<=,1,53,2,0,-,22,23,2
   6.   23,71,2,>=,22,23,2
   7.   23,71,2,>=,22,23,2,0,+,22,29,2
   8.   23,71,2,>=,22,23,2,0,+,23,66,2
   9.   22,41,2,<=,1,29,2,+45
  10.   22,41,2,>=,1,29,2,+13
  11.   22,47,2,<=,1,53,2,0,-,22,41,2
  12.   24,23,2,<=,1,53,2,0,-,22,41,2
  13.   24,28,2,>=,22,41,2
  14.   24,28,2,>=,22,41,2,0,+,22,47,2
  15.   24,28,2,>=,22,41,2,0,+,24,23,2
  16.   22,59,2,<=,1,29,2,+45
  17.   22,59,2,>=,1,29,2,+13
  18.   22,65,2,<=,1,53,2,0,-,22,59,2
  19.   24,45,2,<=,1,53,2,0,-,22,59,2
  20.   24,50,2,>=,22,59,2
  21.   24,50,2,>=,22,59,2,0,+,22,65,2
  22.   24,50,2,>=,22,59,2,0,+,24,45,2
  23.   22,77,2,<=,1,29,2,+45
  24.   22,77,2,>=,1,29,2,+13
  25.   23,13,2,<=,1,53,2,0,-,22,77,2
  26.   24,67,2,<=,1,53,2,0,-,22,77,2
  27.   24,72,2,>=,22,77,2
  28.   24,72,2,>=,22,77,2,0,+,23,13,2
  29.   24,72,2,>=,22,77,2,0,+,24,67,2
  30.   25,50,2,>=,25,48,2
  31.   25,56,2,>,25,54,2
  32.   25,59,2,>=,25,48,2
  33.   21,56,2,>=,1,29,2,0,+,25,59,2
  34.   21,74,2,>=,1,29,2,0,+,25,59,2
  35.   22,23,2,>=,1,29,2,0,+,25,59,2
  36.   22,41,2,>=,1,29,2,0,+,25,59,2
  37.   22,59,2,>=,1,29,2,0,+,25,59,2
  38.   22,77,2,>=,1,29,2,0,+,25,59,2
  39.   25,59,2,<=,1,31,3
  40.   25,61,2,>=,21,45,2
  41.   25,64,2,<=,1,31,3
  42.   25,64,2,>=,25,48,2
  43.   26,33,2,<=,1,31,3,-13
  44.   26,39,2,<=,1,31,3,-13
```

EXHIBIT B.25

ERRORS FOUND IN DATA CLEANING

EDIT SPECS PROGRAM
RANGE OF VALUES

FILE NAME = RAT1.DAT
SPEC. FILE = RAT.RV
NO. OF CASES = 100
PASS NO. = 1

CASE NO.	REC. NO.	CARD	COLUMN	WIDTH	DATA	ACCEPTABLE VALUES	CORRECTION
13068002	25	25	50	2	32	BLANK, 9 - 18, 0, 97, 99,	25/50=32 OK
13068002	27	27	67	4	0185	BLANK, 1400 - 2390,	27/67=1850
14048003	30	2	18	2	18	BLANK, 0 - 16,	2/18=18 OK
14048003	32	4	53	2	18	BLANK, 0 - 16,	4/53=18 OK
14048003	49	21	64	1	3	BLANK, 1, 2, 9,	21/64=9
14048003	50	22	13	1	3	BLANK, 1, 2, 9,	22/13=9
14048003	50	22	31	1	3	BLANK, 1, 2, 9,	22/31=9
14048003	54	26	33	2	99	BLANK, 1 - 25,	26/33=99 OK
14048003	54	26	35	1	9	BLANK, 0, 5,	26/35=9 OK
15028001	57	1	34	3		1 - 999,	1/34=001
15028001	76	20	17	1	6	BLANK, 2,	20/17=666631
15028001	76	20	19	1	1	BLANK, 9,	corrected above
15028001	78	22	31	1	3	BLANK, 1, 2, 9,	22/31=9
16028001	107	23	62	1	2	BLANK, 1,	23/62=626605
16028001	107	23	63	1	0	BLANK, 2,	corrected above
16028001	107	23	64	1	5	BLANK, 3,	corrected above
16028001	107	23	65	1	1	BLANK, 9,	corrected above
16048002	122	10	15	2	00	BLANK, 1 - 16, 99,	10/15=00 OK
16048002	132	20	74	1	3	BLANK, 1, 2, 9,	20/74=9
16048002	137	25	59	2	99	BLANK, 13 - 40,	25/59=22
16048002	137	25	61	2	99	BLANK, 0 - 12,	25/61=26
16048002	137	25	64	2	99	BLANK, 25 - 60,	25/64=26
16048008	158	18	15	1	3	BLANK, 1, 2, 9,	18/15=9
23008001	192	24	43	1	1	BLANK, 3,	24/43=626621
23008007	212	16	58	2	07	0 - 6,	16/58=07 OK
23008007	223	27	67	4	0162	BLANK, 1400 - 2390,	27/67=1629
23008016	275	23	16	2	0	BLANK, 1,	23/16=01
23008017	306	26	33	2	00	BLANK, 1 - 25,	26/33=00 OK
23008017	306	26	35	1	4	BLANK, 0, 5,	26/35=5
23008019	312	4	48	2	96	BLANK, 3 - 85,	4/48=99 OK
23008019	323	15	35	2	99	BLANK, 1 - 84,	15/35=99 OK
23008019	335	27	39	4	0184	BLANK, 1400 - 2390,	27/39=1849
23008019	335	27	67	4	0162	BLANK, 1400 - 2390,	27/67=1629
23008022	356	20	53	1	3	BLANK, 1, 2, 9,	20/53=9
23008022	359	23	42	1	1	BLANK, 3,	23/38=026666621
23008028	382	18	15	1	3	BLANK, 1, 2, 9,	18/15=9
23008028	382	18	42	1	3	BLANK, 1, 2, 9,	18/42=9
23008028	384	20	53	1	3	BLANK, 1, 2, 9,	20/53=9
23008028	384	20	74	1	3	BLANK, 1, 2, 9,	20/74=9
23008028	391	27	67	4	0162	BLANK, 1400 - 2390,	27/67=1629

16048002 check 25/48 true 25/64

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The SRA computer cleaning programs are individually designed to meet the requirements of each study. Special programs are sometimes written for very complex checks or for scoring responses. SRA has written cleaning programs with more than 10,000 specifications for complex surveys. The cleaning programs developed by SRA for the very complex Diagnostic Interview Schedule (DIS) have been purchased by other researchers including the Lovelace Medical Center and the Chinese University in Hong Kong.

The electronic data cleaning programs for the Phase I Telephone Interview, Household Survey and SAQ have already been developed by SRA, approved by the Project Officer, and used successfully to clean the Phase I data. These existing programs will continue to be used to electronically clean the Phase II Telephone Interview, Household Survey and SAQ data. These programs will be modified on an ongoing basis to accommodate changes in edit decisions.

The electronic cleaning programs facilitate the organization and storage of all data (Phase I and Phase II), allowing SRA to develop a comprehensive analysis file. (See 5e.)

The edit programs which were specifically written and tailored to the four study data files; abstracts, telephone interviews, construction surveys and SAQ were developed by SRA for phase I of the project. Since the forms and questionnaires used for Phase I will continue to be utilized in Phase II, SRA will be more proficient in the processing of the data than those of a new contractor.

The programs written, especially for the telephone interview which consists of 26 keypunch decks, were developed to be used in conjuction with other software packages utilized by SRA. The transfer of these programs to another contractor may prove most costly and unrealistic as each research firm generally has individualized internal procedures for the cleaning of study data.

e. Maintain Compatibility of Data with Phase I

Using the electronic editing programs developed in Phase I and SRA's database management software, SRA cumulatively stores all data files for this study and organizes them numerically by ID number within each study component (Telephone Interview, Household Survey, SAQ and Abstract). This comprises a comprehensive analysis file of all respondents in Phase I, which will be expanded to include Phase II data.

An SRA program, developed as a companion to the tracking program, allows SRA to link the study components in order to identify and deliver completed case sets. The initial portion of the Phase I data was delivered in this manner at the request of the Project Officer, accompanied by a computer generated transmittal sheet listing cases numerically by component. Now that this program has been developed, SRA has the capability to organize the data for delivery in any manner that is advantageous to the Project Officer for analysis purposes.

SRA will maintain its current procedures of data storage and organization so that continuity between Phase I and Phase II will be preserved.

Database software in use at SRA has complete compatibility with all major data formats, including ASCII (both comma delimited and non-delimited), DBASE II, DBASE III, DBASE III PLUS, DBASE IV, SPSS and SAS. SRA's export capability from any format to ASCII allows complete data interchange and portability, facilitating the use of statistical program routines written in high level languages

such as Basic, Pascal, C or Fortran. The St. Louis SRA office also has a CATAMOUNT tape drive system which allows for the conversion of data between the diskette and tape media. Tapes are easily uploadable to mainframe systems.

The selection of SRA as the contractor for Phase II of the project will provide standardization of computer programs and Quality Control procedures for both phases of the project.

f. Create Data Files Ready for Analysis

Using the procedures identified in 5d, each component of the data (i.e. telephone, household, SAQ, abstract) is cleaned chronologically in batches of 100 cases/controls. After each batch is cleaned, it is converted to diskette and forwarded to the NCI Project Officer for analysis. Batches are easily added to one another to form cumulative data files. As described in 5e, SRA keeps back-up cumulative data files for all components of the study. This system was used during Phase I and will continue to be used for Phase II.

The Data Manager/Quality Control Director will use statistical software to run frequency distributions and cross-tabulations as requested by the NCI Project Officer.

g. Update and Correct Data as Required

Changes made in the data collection or electronic cleaning procedures often necessitate that corresponding changes be made in the data files. When a data file change is made, SRA documents the change, modifies the data file as indicated by the change, and forwards the updated data file with documentation to the Project Officer. Any problems identified by the NCI Project Officer are discussed with the Data Manager/Quality Control Director and resolved. This correction procedure was implemented in Phase I and will continue to be used throughout Phase II.

H. Specifications for Delivery of Phase I and Phase II Data

For each component of the study, clean data files containing batches of 100 cases/controls are forwarded to the Project Officer. (See 5f) Essentially, the data are cleaned as they are collected, allowing data to be delivered to the Project Officer periodically throughout Phase I and Phase II. Individual batches are easily compiled. This permits analysis to begin prior to completion of the data collection.

The data are delivered to the Project Officer on IBM compatible 3½ inch diskettes in 80 column, fixed field, ASCII format. These delivery specifications have been in use for Phase I and will continue for Phase II.

6. Information Management, Reporting and Documentation

a. Management Information System

Accurate study records are necessary to insure that sampling and screening activities are performed correctly, study populations are identified and tracked,

all documents related to the study are processed in a timely manner, and all data tracking activities are properly monitored. These activities which are maintained by computer, are essential for monitoring the progress of the project.

For Phase I, the SRA Data Management personnel, in collaboration with the SRA Project Director and NCI Project Officer, determined those study elements which needed tracking and recording and the key variables for sorting of study elements. A computer report based on this information was developed by SRA and approved by the Project Officer. Throughout Phase I the computer tracking report has been modified and lengthened. The multi-faceted 50 page report (see Appendix B) is generated monthly and tracks the following:

- Projected Cases for Hospitals Statewide Per Year
- Case Registry Referrals
- Physician Consents
- Eligibility Screening
- Telephone Interview for Cases and Controls
- Household Surveys
- Self-Administered Questionnaires
- Placement of Radon Detectors
- Radon Detector Reminder Calls
- Productivity of the Interviewers
- Zip Code Distribution for Cases
- Zip Code Distribution for Controls
- Retrieval of Radon Detectors

The detail of the computer tracking reports for the current project is extensive for each of the reports generated. The progress of cases and controls are tracked separately with additional tables to monitor:

- study subjects by four separate age groups,
- study subjects by priority ranking, and
- the progress of phases by month.

The computer reports are reviewed during each monthly conference call and additional reports are programmed as required. These reports were extremely valuable during the early phases of the project to adjust the work, and to contain costs while creating an agenda for prioritizing field assignments.

The programming of this report has required extensive time by the Programmer/Analyst during the past two years. The transfer of these programs to another contractor would be difficult, costly and time consuming.

In addition to the computerized status reports, SRA's Project Director submits narrative reports monthly, semi-annually and annually to the NCI Project Officer. These reports describe: study progress, problems encountered, resolutions or proposed resolutions to problems, frequency distribution of variables, a summary of Radon measurements to date, quality control activities of all aspects of the project.

The above reporting procedures have been carried out throughout Phase I and will continue in Phase II.

The final progress report will include a summary of all information contained in previous reports. It will describe sampling, screening procedures, training of abstractors, training of SRA interviewers and Radon field clerks, training of editor/coders, data collection procedures for abstracting, interviewing, and obtaining information on current and previous residences of cases and controls, and procedures established for placement and retrieval of dosimeters. The final report will also include completion rates for telephone interviewers, for structural data on current and past homes of study subjects, and for placement and retrieval of Radon dosimeters.

b. Documentation of Study Decisions

All documentation and organization of the individual study phases will be carried out for Phase II in the same manner in which they were carried out for Phase I; that is Phase I and Phase II study documentation will be completely compatible.

All letters, forms, questionnaires, manuals, and other study documents were developed in CPT word processing (DOS, ASCII). These CPT files are easily convertible to mainstream word processing software formats (i.e WordPerfect) for use on a microcomputer. Copies of all documents are stored on diskette in fireproof cabinets and maintained for at least three years subsequent to the study's termination.

All survey materials are stored in locked file cabinets or in a locked room and are accessible only to supervisory personnel and employees working directly with the material. Specific internal data collection and data handling procedures SRA uses to ensure confidentiality include the following:

- Unless specifically instructed otherwise, employees or field workers are not permitted to abstract data, interview a respondent or process data from a respondent whom they know personally.
- While in company offices, survey data containing personal identifiers are kept in locked file cabinets or a locked room when not being used each working day in routine survey activities.
- For confidential information, identification numbers are assigned to respondents prior to creating a machine-processible record. Personal identifiers such as name, address, telephone number and Social Security Number are not a part of the data file for data collection instruments. A file with identifiers and case identification is kept apart from the hardcopys of the questionnaires and data tapes/diskettes in a separate, locked storage area. These files are referred to only when incomplete response forms make it necessary to retrieve information from respondents. Access to these linkage files is restricted to supervisory-level personnel.
- At the end of the period of survey performance, the Field Director arranges for proper storage and disposition of survey data, depending upon particular contractual requirements for storage or disposition.
- The Field Director ensures that survey practices adhere to the provisions of the U.S. Privacy Act of 1974 with regard to surveys of individuals performed for the Federal Government.

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These confidentiality procedures have been in place throughout Phase I and will continue for Phase II.

For this study, SRA maintains several logs that record the development of study design, conduct and decision making. These include:

- A field log, which is comprised of field memos, documentation of telephone calls and other information that relates to changes and updates in data collection activities.
- An edit/coding decision log, which documents editing and coding decisions. The log includes a description of each editing/coding problem, a description of the resolution, the date it was resolved, and the initials of the SRA manager or NCI Project Officer who authorized the decision.
- A respondent log, which documents all SRA office telephone contacts with respondents, many of which call in on the 800 number.

7. Quality Control and Standardization

Quality Control refers to a set of measures undertaken by SRA to insure that data collected are reliable and valid. These measures prevail throughout the study to insure that data are accurate, timely, consistent, and complete. Each data collection instrument, whether it be a telephone, mail, or personal interview, medical abstract, or other instrument, is specifically designed to fulfill the objectives of the research protocol. Similarly, study procedures and record-keeping mechanisms are designed to insure that high quality data are obtained in an efficient manner. The purposes of the quality control process are to:

- Produce data that are as error-free as possible;
- Collect data designed to answer specific research questions in a form compatible with computer data processing and analysis;
- Insure that data collected measure what they are intended to measure;
- Produce data comparable to relevant research on the topic by employing standardized and proven questions and procedures whenever possible.
- Insure consistent results by the use of standard procedures so that the data collection instrument will yield the same results when used by different individuals;
- Provide documentation of the steps involved in data collection and data procession;
- Design survey questions to yield unbiased answers from respondents;
- Aid in tracking and locating respondents to insure a high response rate;
- Insure that data are collected in a timely and efficient manner.

Quality Control measures begin in the design stage of the research project and continue throughout data collection and data processing. Quality Control measures taken in the early stages of the research project help to prevent problems during the data collection and processing stages.

a. Monitor Study Progress

The SRA Project Director monitors the progress and cost of all stages of the project. She keeps the NCI Project Officer updated on all activities and problems and acts as a liaison between NCI and SRA staff, Cancer Registry staff, and the staff of all other parties cooperating on this study.

The Study Manager monitors the quantity and quality of the work of all SRA personnel at the St. Louis Office including the Field Directors, Registry Coordinator, Interviewers, Radon Field Clerks, Quality Control staff, Data Processing Staff and the Clerical Staff. She utilizes time sheet information and computerized personnel performance reports, as well as regularly scheduled conferences (by phone or in person) with each employee to evaluate productivity.

The Field Director monitors the productivity of the Tumor Registry Coordinator via regularly-scheduled telephone conferences. Any instances where reporting deadlines cannot be met would be immediately reported to the Project Director who would relay this information to the NCI Project Officer.

The Data Manager/Quality Control Director is responsible for monitoring the quality of all raw data collected on the study as it passes through the stages of preparation including manual editing, coding, and electronic data cleaning.

b. Report Verification, Discrepancy and Error Rates

Written documentation is kept of all verification and validation activities, including discrepancies found and error rates. Results of these activities are included in regularly written reports submitted to the NCI Project Officer. The documentation is available for the Project Officer or Assistant Project Officers to examine at any time. The Project Officer or Assistant Project Officers may also check samples of abstracting, coding, keying, interviewing or other work at any time.

c. Institute Corrective Action

Any deviations from protocol or errors in work which are found are reviewed with the employee responsible for them. If necessary, re-training of the employee is conducted.

d. Conduct Quality Assurance Checks as Requested

Approximately 10% of Telephone Interviews are validated by calling and re-asking pre-selected questions. (See 5a.) If requested by the NCI Project Officer, subjects are re-interviewed. Household Survey data are also validated by calling approximately 10% of the occupants and re-asking pre-selected items. Approximately 5% of abstracts will be verified through re-abstraction by an editor/coder. All validation activities are conducted under the supervision of the Data Manager/Quality Control Director.

e. Monitor Work Conducted Under Subcontractors

There have been no subcontractors on Phase I of the study, other than printing and keypunching firms. Work that is conducted by these firms is closely monitored by the Study Manager for quality, cost, and timeliness of delivery.

It is expected that Phase II will be identical to Phase I in terms of conduct of work by subcontractors. Monitoring will also be identical.

f. Monthly Conference Call

Once a month, a regularly scheduled conference call is conducted with the NCI Project Officer, Missouri Cancer Registry Coordinator, the SRA Project Director and the SRA Study Manager to discuss the monthly computer report, data collection issues, changes in procedure, and all aspects of quality control activities. Other personnel such as the Tumor Registry Coordinator, Program/Analyst, or Date Manager also participate if the conference call at appropriate times.

Two days prior to the call a packet is mailed to each participant. Included in the packet is an agenda for the call, a current computer report, copies of items for the decision log that need to be addressed, a list of quality control activities and any other items pertinent to the call. Additional conference calls are scheduled and held as needed.

C. Organization, Staffing and Management

The organization, staffing and management of the Case/Control Study, Residential Exposure to Radon draws upon SRA's experience and resources in conducting epidemiological case/control studies involving medical abstracting, and telephone and field interviewing. The technical staff currently assigned to the project will be responsible for continuing to achieve study objectives. It is important to have a clear understanding of job descriptions and the level of involvement expected of each person as the study progresses. (See Manhours Allocated Per Task, EXHIBIT C.1) It is equally important to understand the relationship of each staff member's job to those of other staff members and the Project Officer. (See Management Plan, EXHIBIT C.2).

The study team that has been working on the current project will remain intact for this project. This team will provide much expertise in management of this complex project and are the persons responsible for developing the final study plan, questionnaires, forms and procedures, training manuals, coding schemes, data cleaning programs, and computer tracking reports.

The technical staff for this contract includes the Project Director, Study Manager, Tumor Registry Coordinator, Field Director, Quality Control Director/ Data Manager, and Programmer/Analyst. Experience of these personnel is presented in Section D: Personnel. Their curricula vitae are provided in Appendix A.

1. Project Director

The Project Director will have primary responsibility for continuing to monitor all phases of the fieldwork. She will be responsible for developing procedures to incorporate the retrospective cases into the study protocol. She will work with the NCI Project Officer in making decisions concerning implementing or changing field procedures. She will write the monthly, semi-annual and annual reports and monitor the budget, and participate in the monthly conference calls to discuss the progress of the field effort. The Project Director is located in Baltimore, Maryland and will attend meetings at NCI if necessary.

2. Study Manager

The Study Manager will monitor the technical staff in the St. Louis office including the Field Director, quality control activities and the assignment of support staff to the project as needed. In addition, she will monitor the activities of the Tumor Registry Coordinator in Columbia, Missouri. As in the past, she will continue to handle any inquiries from agencies, physicians, and the media. She will be responsible for recruiting the additional telephone interviewers and radon field clerks needed for the project. When necessary, the Study Manager will conduct on-site visits to individuals or organizations in order to enlist their cooperation. The Study Manager will be responsible for informing the Project Director of all liaison activity with registry personnel and other relevant parties. In turn, the Project Director will report progress and special circumstances to the Project Officer.

Throughout the study, the Study Manager will be responsible for assuring that data collection complies with all established procedures and timelines. She will communicate to the Project Director any difficulties encountered in implementing the procedures, document these difficulties, and suggest alterations for avoiding and/or overcoming them. She will keep a decision log of problems that occur and the decisions made during the field period. She will monitor the time and mileage reports and productivity reports of study personnel. The study manager will also participate in the monthly conference calls and bring any problems to the attention of the Project Director. Ms. Henderson is available to attend meetings at the Cancer Registry in Columbia, Missouri.

3. Field Director

The Field Director will be responsible for continuing to oversee the day-to-day monitoring of the fieldwork under the supervision of the Study Manager. She will take referrals from the Tumor Registry Coordinator, make sure that advance letters are generated and sent out in a timely manner, assign responsibilities to the clerical staff, assure that records are filed in an accessible manner, make assignments to both the telephone and field interviewers, review all completed work, prepare forms for data entry, batch field visits in geographic areas, speak to reluctant respondents, and contact landlords for permission to place dosimeters.

Once dosimeters are placed in a household, she will be responsible for making sure that the reminder calls are completed and postcards are mailed. She will have her support staff send out the return packets for the dosimeters one year after their placement, bring any problems with harvesting to the attention of the Project Director or Study Manager and batch dosimeters for mailing to the lab for analysis. She will also verify that results are received from the lab, and sent to respondents and/or landlords.

4. Assistant Field Director

The Assistant Field Director will help the field director in any way necessary. She has been working on this study for the past 18 months and has a clear understanding of all tasks required for the project. She will take reports from field clerks and assist in the assignment and monitoring of both the telephone and field interviewers. She will be responsible for mailing supplies to the field staff. She will be responsible for generating individualized letters addressing the concerns of individual respondents and their appropriate gate keepers to avoid potential problems.

5. Data Manager/Quality Control Director

The Data Manager/Quality Control Director will be responsible for technical direction and coordination of all computer-related systems and tasks, providing the liaison between the data collection aspects of the study and the data reduction process. Implicit in this position is the responsibility for assuring that the data processing plan and its implementation are consistent with NCI analysis objectives. In the execution of her responsibilities, she will work in close cooperation with the Project Officer, the Project Director, and the Study Manager during all tasks of the study. The Data Manager will be knowledgeable about the computer resources available and able to advise on the system design most appropriate for a given need, and be experienced in supervising the work of programming and data processing personnel.

During the current project, the Data Manager/Quality Control Director has reviewed forms item-by-item to ensure compatibility with data reduction procedures and has made certain that forms were designed to facilitate data processing and minimize chances for keying error.

The Data Manager has also been responsible for advising on the software most appropriate for efficient production on a specific task and for designing, or reviewing the design of, automated systems for data collection, editing and tracking. The Data Manager has also supervised the assembly and maintenance of the databases, ensured the verification of data entry, the adequate and up-to-date documentation of all data files, and the timely production of all computer-generated reports and the final data tape.

In relation to Quality Control, she will continue to oversee the effort of the editing, coding and data cleaning of the telephone interview, household survey and nutrition questionnaire. She will monitor the accuracy and productivity of her staff by completing second edits on 10% of each editors work. She will work with the NCI Project Officer on edit decisions and keep a log of these decisions throughout the field period.

6. Programmer

The Programmer/Analyst will continue to be responsible for any changes required in the computer reporting system she developed for this study. She will also perform the sampling effort for the DMV and HCFA tapes for the study, and will program any special requests made by the NCI Project Director. The Programmer Analyst will be responsible for the production of the final data tape. The Programmer/Analyst will be under the direct supervision of the Data Manager.

7. Tumor Registry Coordinator

The Tumor Registry Coordinator will contact each hospital in Missouri several times a month to encourage rapid case ascertainment of prospective cases. In addition, she will make circuit trips to hospitals in the state to abstract records for possible eligibility in the study. She will review the abstracts sent to the Cancer Registry in Columbia, Missouri to make certain that they are complete and accurate and assign the necessary coding and staging. For the retrospective cases she will access the files and microfiche to ascertain cases for inclusion in the study. She will complete the abstract forms for the retrospective cases. The Tumor Registry Coordinator will be located in Columbia, Missouri to facilitate access to the Cancer Registry there.

The Tumor Registry Coordinator will be under the direction of the Study Manager. She will refer all cases to the SRA office in St. Louis.

8. Other Personnel

a. Telephone Interviewers

SRA will continue to use the three experienced interviewers currently on the project for this new phase of work. In addition, three experienced telephone interviewers from our St. Louis office will be trained to handle the increased

work effort. Cases will be referred individually as they are identified and two age-group matched controls will be selected at that time. Telephone interviewers will trace, screen, and interview respondents. Upon completion of the telephone interview they will explain the field visit. These interviews will be administered from the St. Louis office.

b. Radon Field Clerks

The Radon Field Clerks will be responsible for conducting the household construction survey, the nutrition questionnaire and the placement of two radon dosimeters in each current and former home of all study subjects.

Radon Field Clerks will be located throughout the State of Missouri to provide geographic proximity to the households that are included in the study. The eight Field Clerks currently working on the project will continue to make field visits and an additional 10 field personnel from SRA's experienced staff would be recruited and trained for the project.

The Radon Field Clerks will perform their responsibilities in accordance with written procedures established by the SRA Project Director and the Project Officer. They will be under the direct supervision of the Field Director to whom they must routinely provide accurate records of the locations of all dosimeters.

c. Editor/Coders

SRA maintains a staff of experienced coders under the direct supervision of the Data Manager/Quality Control Director. The editor/coders currently working on the project will continue to be responsible for manually editing and coding each interview, logging in edit decisions and reviewing edit corrections with interviewers. For this project the editing staff will edit and code the medical record abstracts, the telephone interview, the household construction survey and the nutrition questionnaire.

Each of the questionnaires used in this project are of a very specialized nature. The medical record abstract requires cancer coding and staging. The telephone interview is quite extensive and requires a family history in several sections in addition to ICD-9 and occupational coding. The Household Construction survey requires that decisions be made regarding various types of structures, alterations to the original structure, and specifics about heating systems. The nutrition questionnaire is very compact and deals with a large variety of food. This instrument requires an understanding of portion sizes and usual portions per week.

d. Data Cleaners

The data cleaning for the project will continue in the current manner for the new portion of the project. This task consists of manually checking and correcting all errors indicated by the electronic data cleaning programs that have been written for the study. Each batch of data is run through these programs until they are error free and the interview booklets are manually corrected. This task is performed under the supervision of the Data Manager/ Quality Control Director.

e. Data Entry

Data Entry includes those tasks associated with logging of all record keeping forms, producing labels needed for forms in the fieldwork and generating weekly reports on all phases of the study progress. The tracking programs for this study are very complex. Each phase of the study is tracked independently by several types of variables. The report for the harvesting of the radon dosimeters alone allows for 27 different variations in the combination of types of detectors placed and retrieved and their purpose.

f. Clerical

Clerical tasks for this project are numerous and quite varied and are currently performed by support staff in the St. Louis office. These tasks include listing from the telephone interview each household where the respondent has lived for the past 30 years in order to create the sample for the field survey, sending out physician, landlord and respondent letters, contacting households both by telephone and with postcard reminders to check that the dosimeters are still in place, tracing telephone numbers for next of kin of deceased respondents, mailing supplies to interviewers, preparing interviewer assignments, filing cases received each day, typing memos and letters, sending mailing packets to households eligible for harvesting and preparing dosimeters for analysis by the lab.

D. Personnel

SRA's permanent staff of skilled professionals currently working as a team on the Case/Control Study of Residential Exposure to Radon will be available to conduct all aspects of the study. The study team was involved in the current project during the development, training and de-bugging of the field procedures. The team of professionals chosen for this project have worked together on many previous projects and will bring a level of cooperation to the study that will greatly facilitate its successful completion. For each named staff person, a curriculum vitae is included in Appendix A.

Job descriptions and past experience are highlighted below for key personnel.

1. Project Director: Sandi Ezrine

SRA will appoint Ms. Sandi Ezrine to continue as the Project Director of the Case/Control Study, Residential Exposure to Radon and Lung Cancer Among Nonsmoking Women in Missouri. As Project Director, she will be responsible for working with the NCI Project Officer throughout the contract period, for coordinating and managing the staff necessary to execute the contract, and for budget management and report writing. Ms. Ezrine was responsible for working with the NCI Project Officer in developing the forms and procedures currently being implemented for this project.

As a Project Director, Ms. Ezrine has the experience and expertise to evaluate all aspects of her staff's work and is able to direct them in systems and forms design, planning, troubleshooting, and management.

Ms. Ezrine has had over ten years of experience in the survey research field, including planning, organizing, and managing epidemiological and health care studies. As SRA's Research Director, she represents SRA at professional and client meetings, prepares company proposals in response to federal and private procurement requests and develops and monitors all aspects of ongoing studies, including financial concerns. For the last seven years, Ms. Ezrine has been responsible for the overall supervision of SRA's technical staff.

Ms. Ezrine has served as the Project Director for many studies; the most recent of which include: Case/Control Study of Residential Exposure to Radon, Racial Variations in Glaucoma: Prevalence and Severity, and the Study of Prenatal and Neonatal Factors in Childhood Strabismus. Her work on these and many of SRA's other major contracts demonstrate her experience in the successful execution of the responsibilities required of the Project Director of this contract. This experience includes:

- interaction with researchers in planning and developing study protocols;
- development of data collection forms, questionnaires and instructional manuals;
- development of complex record-tracking and data collection systems;
- interaction and coordination of data collection activities with care providers;
- coordination and direction of data processing and quality control procedures;

- utilizing cancer registries to identify respondents;
- coordination of multi-site data collection efforts;
- development and monitoring cost projections;
- problem-solving; and
- reporting.

Ms. Ezrine has directed many studies involving interviews with cancer patients, including three studies utilizing a state cancer registry as the source for the sample. Samples for the Study of Breast Cancer Screening and Detection Programs for the Cancer Control Program, the Survey of Cancer Rehabilitation Related Problems and the Study of the Needs of Cancer Patients in the Last Month of Life as Reported by Their Significant Other, utilized samples from the Pennsylvania State Cancer Registry. In these and numerous studies, Ms. Ezrine has successfully executed the primary responsibility for training medical abstractors and interviewers, developing abstract and interview forms and designing and managing data collection, preparation, and processing systems. She has repeatedly demonstrated her ability to understand the scope of work for projects, develop and implement efficient systems for data collection, and meet deadlines of the contractor in a timely manner. A detailed account of Ms. Ezrine's experience can be found on her curriculum vitae.

2. Study Manager: Patsy Henderson

Ms. Patricia Henderson will continue as the Study Manager for the Case/Control Study, Residential Exposure to Radon. As Study Manager, she will be responsible for coordinating and supervising the technical staff in the St. Louis office, assuring that procedural guidelines are followed and that problems associated with these guidelines are identified and brought to the Project Director's attention.

Ms. Henderson has had over sixteen years of experience in survey research. She has been employed by SRA for eight years as Director of Mid-West Operations and maintains her base of operation in St. Louis. As Director of Mid-West Operations, she is responsible for liaison work with researchers in academic institutions, private companies, and local and state agencies located in the mid-west. In this capacity, she has supervised and assisted in the design and implementation of data collection activities of major SRA contracts, through which she has demonstrated the following expertise:

- coordination with medical care providers;
- coordination of multi-site data collection;
- longitudinal tracking of sample population for up to four follow-up waves, including tracing and locating;
- collecting data on highly sensitive subject matter requiring strict confidentiality;

- supervising field and support personnel;
- the ability to recognize problems as they appear and implement corrective action; and
- achievement of high response rates.

Ms. Henderson has been the Study Manager for the Case/Control Study of Residential Exposure to Radon since its inception. She has established an excellent rapport with public and private agencies, the tumor registry and the media concerning this project.

Ms. Henderson has notable expertise recruiting and maintaining the cooperation of health care providers in data collection activities. This expertise was best illustrated in her successful field direction of the Evaluation Study of Program to Consolidate Services for High Risk Young People (Robert Wood Johnson Foundation) in which she persuaded the directors of 42 nationwide multi-service clinics to participate in an evaluative study of their own programs. Ms. Henderson was successful in developing data collection procedures and maintaining participation in each clinic throughout a two-year study period. In addition to demonstrating her ability to develop relationships necessary to achieve research objectives, she has demonstrated the ability to train and supervise other staff in the techniques of building successful relationships.

In addition to Ms. Henderson's experience in survey research techniques, she has specific experience managing a previous study of environmental hazards in the St. Louis area, the Health Effects of Environmental Hazards Study. Through her direction of this study and other research efforts, she is well acquainted with the professional community in Missouri and has access to qualified local personnel.

3. Field Director: Joan Huber

Ms. Joan Huber will continue as SRA's Field Director for the Case/Control Study, Residential Exposure to Radon. Ms. Huber has over eighteen years of experience in survey research. Over the past eight years, she has been employed by SRA/St. Louis in a variety of capacities including Field Supervisor, Recruitment Specialist and Interviewer.

Ms. Huber's efforts on the Case/Control Study of Residential Exposure to Radon have been outstanding. She has been able to obtain the cooperation of both cases and next of kin at a particularly traumatic time. She has developed excellent systems for keeping track of each segment of a case set. She has gained much knowledge about the landlords throughout the state of Missouri and methods for gaining their cooperation. In addition, she has been able to keep both the telephone and interviewing staff motivated during the complex project.

Ms. Huber's past experience and demonstrated skill is well suited to the position of Field Director for this study. As a supervisor for the Evaluation Study of Program to Consolidate Services for High Risk Young People, she was responsible for training interviewers and supervising a team of abstractors in the on-site review of medical records in multi-service clinics. In order to maintain the cooperation of clinics throughout the field period, she was active in troubleshooting data collection problems as they occurred.

Through her work on this study, as well as on many other studies, Ms. Huber has demonstrated exceptional skill in the following areas:

- establishing and maintaining working relationships with data providers;
- managing telephone and field inteviewers;
- anticipating and addressing problems in data collection workflow;
- managing complex clerical efforts; and
- monitoring and supervising concurrent data collection work efforts.

In addition to being experienced and skilled in survey research techniques, Ms. Huber is knowledgeable about hospital health care decision making processes and is familiar with the Missouri health care system.

4. Data Manager/Quality Control Director: Susan Butler

Ms. Susan Butler is employed as SRA's Data Manager/Quality Control Director for the St. Louis office. In this position, she routinely executes all data management and quality control responsibilities for ongoing studies and will assume the direction and coordination of all computer-related systems and tasks for this contract as well. It will be her responsibility to assure the compatibility of the data processing system with NCI objectives and the timely development of computer edit programs, tracking systems, reports and documentation. As part of her duties on the Case/Control Study of Residential Exposure to Radon, Ms. Butler has written the data cleaning programs for the three interview schedules, developed coding procedures, and designed procedures for yearly delivery of clean data sets. She has successfully managed both the quality control and computer tracking efforts required for the current project.

Ms. Butler's current job duties demonstrate her expertise in performing the data management responsibilities required for the execution of the NCI contract, including:

- interacting with researchers in assessing and planning for data processing needs;
- writing computer edit specifications;
- working with programming and other staff to develop receipt and control systems, data verification, cleaning, and analysis programs;
- supervising programming and data entry personnel;
- monitoring quality control operations;
- consulting with researchers in the development of instrument specifications and formulation of edit/coding specifications;
- anticipating edit problems and devising methods for problem circumvention;

- training and supervising editors and coders;
- maintaining procedural documentation; and
- assisting in the preparation of reports.

5. Programmer/Analyst: Christine Thompson

Ms. Christine Thompson is SRA's Programmer/Analyst. She will continue to be responsible for the programming tasks associated with the NCI contract. Ms. Thompson has had over sixteen years of experience in data preparation and analysis. During this time, she has been responsible for programming, sampling, and both parametric and non-parametric statistical analysis.

For the current project, Ms. Thompson was responsible for developing complex computer tracking programs to monitor the progress of cases, controls, and former residences during all phases of the study. She will continue to be responsible for the development of any additional tracking programs for this new effort.

In addition, Ms. Thompson will also continue to be responsible for the sampling of controls from the DMV and HCFA tapes annually.

6. Tumor Registry Coordinator: Carlene Anderson

Ms. Carlene Anderson will continue as SRA's Tumor Registry Coordinator for the project. During the current contract, Ms. Anderson has been successful in keeping in close contact with the hospitals throughout the state of Missouri to insure rapid case ascertainment. Her contact includes both telephone and in-person visits. She has established good working relationships with both tumor registrars and hospital directors during the current project.

Ms. Anderson has worked with Tumor Registries for the past 12 years. She is most knowledgeable about cancer coding and accessing medical records. This experience enables her to ascertain whether records are accurate and complete.

E. Organizational Qualifications

1. General Background

Survey Research Associates was incorporated as a private research firm in 1978. Prior to this incorporation, many of the key personnel now with SRA comprised the Survey Research Unit of Johns Hopkins University, which operated under University sponsorship from 1973-1978.

Since its incorporation in 1978, SRA has continued to provide survey research services to universities, private corporations, foundations; and local, state and federal government agencies both locally and internationally. SRA conducts large scale, complex, and multi-site studies which focus on medical, behavioral, social science, and other health-related issues.

SRA's capabilities include those personnel and facilities necessary for a broad range of services. A permanent technical staff is available in each of SRA's offices. Skilled professionals assist clients in all phases of survey research, from sample design to data analysis. The field staff includes a nationwide network of supervisors, interviewers, abstractors, editors and coders who have years of experience in survey research work. These highly skilled personnel assure a high level of quality and productivity.

2. Facilities

SRA corporate headquarters are located in Baltimore, Maryland with permanent offices in Durham, North Carolina and St. Louis, Missouri. SRA also establishes field offices in other locations as necessary.

a. Baltimore, Maryland

SRA's headquarters are located in Baltimore, Maryland, within a few miles of Baltimore's research universities, and one hour from the National Institutes of Health and other federal government contractors. The headquarters include private offices for professional staff and large areas for training, conferences, editing, data processing, and telephone interviewing.

- Telephone Center - Telephone carrels are located in two separate centers. Each telephone center has a supervisory station equipped with a telephone override to provide access to interviewing stations for monitoring and validation of interviewers' work. The hours of operation for the telephone center are adapted to meet the requirements of individual projects, e.g. day, evening, and weekend. One center is equipped with computer terminals for Computer-Assisted Telephone Interviewing (CATI).

- Data Processing Department - The data processing facilities include IBM-compatible networked computers and laser printers. The area is utilized by the programming, data management, data entry, and data cleaning staff. Tape drives, modems for accessing mainframe computers, IBM compatible PC's, and a tape cartridge back-up system are located in the data processing center. Equipment is upgraded to keep pace with current technology and client needs.

The programming staff is experienced in data and system management programs. SPSS, DBase, Paradox, and various other types of software programs.

All aspects of a study are computerized. This includes generation of master lists, labels, tracking the progress of the fieldwork, summary reports, data cleaning, code books, and financial reports.

- Word Processing Department - The word processing department uses IBM compatible networked word processors equipped with laser printers. Various programs, such as CPT Word Processing, Ventura Desktop Publishing, and Word Perfect are used to generate questionnaires, forms, training manuals, question-by-question specifications, respondent letters, reports, and proposals.

- Quality Control Department - The Quality Control area contains resource books for coding and a common area for completion of editing and coding procedures. SRA editors have been trained in International Classification of Disease, Version 9 (ICD-9) procedures as well as census and other standardized types of coding.

- Library - A library is located on the premises which contains resource publications and books in the field of survey research and health-related topics. All materials from previous projects completed by SRA are kept on file including manuals, forms and questionnaires which can be used as references for future projects. Resources such as maps, telephone directories from many states, criss-cross directories, Hanes directories, and zip code indexes are also kept in the library for tracing efforts.

- Personnel Department - The Personnel department maintains a computerized list of personnel, including experienced interviewers and supervisors, who have worked for SRA. SRA also has access to a nationwide network of interviewers, supervisors, and abstractors who freelance to major survey research companies and government agencies.

- Training Center - SRA has the facility to train up to 35 people in-house. For larger trainings, local hotels and conference centers are available. SRA has conducted two-week trainings of 100 interviewers, editors, and support staff, both locally and out-of-state. Trainings for multi-site studies are generally held in one of our permanent office sites (St. Louis, Baltimore, Durham), or at a site convenient for the client, such as Washington, D.C.

b. Durham, North Carolina

The North Carolina office of Survey Research Associates is a full-service survey research facility. Located adjacent to the Research Triangle Park, the office is easily accessible by the area's major universities, government agencies, and other research organizations. The office routinely conducts 20 or more studies at one time.

Major clients include the Epidemiology Branch of the National Institute of Environmental Health Sciences (NIEHS) and the Schools of Public Health and Medicine of the University of North Carolina at Chapel Hill. The range of services provided include consultation on study design and data collection forms, collection of data by a variety of mechanisms, data processing and

quality control, and data analysis. The office staff have experience in cross-sectional and longitudinal research projects, administration of complex study designs involving multiple data collection activities, and experience in recruiting study subjects from community and clinical populations.

The types of data collection conducted by the North Carolina office include in-person, telephone and Computer-Assisted Telephone Interviewing (CATI); medical record abstracts; employment history abstracts; and biological specimen collection. The content areas of studies include environmental and reproductive epidemiology, occupational mortality studies, and health education research. The North Carolina office of SRA has conducted studies throughout the state of North Carolina, in other locations througout the United States and in five foreign countries.

c. St. Louis, Missouri

SRA's Midwest office is located in St. Louis, Missouri. The Midwest office was established in 1981 and continues to serve clients in the Midwest and coordinate complex multi-site studies nationwide. The Midwest office has established a reputation for the successful handling of complex national, large-scale, longitudinal studies. The St. Louis office has coordinated the efforts of as many as ten different studies at one time. With the support of one of SRA's research directors during the development of the study, the St. Louis staff oversees and coordinates all of the field operations for each project.

The physical facilities of the St. Louis office are convenient to the St. Louis area business districts and Washington University. The offices are organized by department and include; private offices for technical staff, a training/conference room, a data processing center, a data cleaning center, and an editing center.

Technical staff located in this office include: the director of Midwest operations, field directors, supervisors, a data manager, programmers, editors and other support staff.

The data processing department uses IBM networked computers, laser printers, a tape back-up system, modems and a tape drive. The software library is quite varied and includes; D-Base, SPSS, Word Perfect and Data Perfect. The computer capabilities enable the office to provide compatible data to clients and is upgraded as necessary. The St. Louis office also has BITNET and FAX capabilities.

All aspects of data management in the St. Louis office are computerized for each study. This includes a tracking and reporting system, regular progress reports, special reports as required, data cleaning programs, and management reports.

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IRIGINAL

CASE CONTROL STUDY OF RESIDENTIAL EXPOSURE TO RADON AND LUNG CANCER AMONG NONSMOKING WOMEN IN MISSOURI

TECHNICAL PROPOSAL

MAO / RFP No. NCI-CP-95654-13

APPENDICES

Submitted by:

NCI Master Agreement Holder #NO1-CP-71096

Survey Research Associates, Inc.
6115 Falls Road
Baltimore, Maryland 21209
(301) 377-5660

APPENDIX A

CURRICULUM VITAE

CURRICULUM VITAE
SANDI EZRINE

Education

1981 M.S., Johns Hopkins University, (Applied Behavioral Counseling)
1978 Johns Hopkins University, Graduate Training, (Special Education)
1967 B.A. (with honors), University of Maryland, (Social Science)

Work Experience

1980 - Present Survey Research Associates, Inc.
6115 Falls Road
Baltimore, MD 21209

RESEARCH DIRECTOR

Responsibilities include writing proposals and overseeing all aspects of data collection, including: study design, development and formatting of questionnaires, planning and implementing fieldwork, establishing systematic receipt and control procedures, monitoring technical staff, writing training manuals, leading and coordinating training groups, developing computer tracking programs, analyzing budgets and monitoring expenditures, systems analysis, interfacing with data management personnel, consulting and reporting to clients, and writing final reports.

1987 - 1990 PROJECT DIRECTOR: **Case/Control Study of Residential Exposure to Radon.** A three-year, state-wide, case/control study of 850 women in the state of Missouri. Cases, non-smoking women who were recently diagnosed with lung cancer through the Missouri Cancer Registry, and controls were screened for eligibility and completed an extensive one-hour telephone interview. All residences of respondents for the past 30 years were accessed; a construction survey was completed and two radon dosimeters were left in the household for one year. Dosimeters were harvested and analyzed. Data for all phases of the project were integrated to calculate life exposure to Radon for each respondent. (*Client: National Cancer Institute*).

1988 - 1993 PROJECT DIRECTOR: **Client Outcome Study.** A five-year evaluation project of the mental health service delivery system in four sites. The sample of chronically mentally ill patients had two components: 600 patients being released from mental hospitals after an inpatient stay and 250 chronically mentally ill patients who had received Section 8 housing certificates. The hospital sample was comprised of two cohorts who were interviewed at three points in time over a one-year period. The Section 8 sample was interviewed at four points in time over a four-year period. In addition, the name of a case manager was provided who was responsible for each client's delivery of services, and was asked to complete an interview booklet about each client. Developed on-going referral procedures for coordination of liaisons in mental hospitals in four cities with SRA's field staff. Wrote instructional manuals and complex field procedures for this multi-site, multi-phase, multi-wave project. (*Client: University of Maryland, National Institutes of Mental Health, and the Robert Wood Johnson Foundation*).

1989-1993 PROJECT DIRECTOR: **Prevention Intervention Research Center Grant (PIRC).** Consulted on study and questionnaire design, wrote instructional manuals, developed complex procedures for obtaining consents, and interviewing parents of 2,252 students in 119 Baltimore City Public Schools. The sample consisted of children who had been identified during first grade and were assigned to either an intervention or control group. This study was a follow-up of those children three to four years later to determine their current behavior in school and at home. Complex computer tracking and daily reporting processes were required for informing the PIRC staff of the progress of the study by child, by class, by school, each day. (*Client: Johns Hopkins University School of Hygiene and Public Health.*)

1989-1991 PROJECT DIRECTOR: **Health Care Finance Administration Demonstration Project.** Developed procedures to monitor the progress of the fieldwork with a sample of 12,000 Medicare recipients. Motivated the field staff to complete 4,500 interviews with elderly respondents in a very brief field period. Respondents were traced and screened for eligibility. Those persons whose physician had agreed to participate in the study were eligible for an interview. Respondents completing an interview were randomly assigned to either an expirimental or control group. The expirimental group was sent a voucher to be given to his/her physician for preventive medical care not usually paid for by Medicare. The management of this study was intense and complex in terms of computer programs and technical expertise. A two-year follow-up is planned with the study population. (*Client: Johns Hopkins University School of Hygiene and Public Health.*)

1989-1990 PROJECT DIRECTOR: **Sexually Transmitted Disease and Fertility.** Consulted on questionnaire design, developed forms and procedures for a 3- and 6-month telephone interview with unmarried patients in a STD clinic. Wrote instructional manuals, developed computer tracking processes, and supervised the technical staff. The sample consisted of 1,000 clinic patients who were interviewed at baseline by clinic staff and referred to SRA for follow-up. (*Client: Johns Hopkins University, Department of Population Dynamics.*)

1989-1990 PROJECT DIRECTOR: **Back Injuries in Baltimore City Municipal Employees.** This project was the first to attempt to obtain information about back injuries using a standardized interview schedule rather than the professional expertise of an ergonomist. The instructional manual and training of interviewers included the concepts of ergonomics. 600 in-person interviews were completed with city employees who had been injured on the job and selected controls. Interviews were completed within seven days of identification. The purpose of the study was to examine ways in which future injuries can be prevented or their severity reduced. (*Client: School of Hygiene and Public Health, Johns Hopkins University.*)

1989-1990 PROJECT DIRECTOR: **Childhood Victimization and Later Violent Behavior Study.** Consulted on study complex questionnaire design, using the DSM-IIIR. The sample consisted of respondents who had been abused or neglected as children twenty years ago, and matched controls who had been selected from school and municipal records. The purpose of the study was to explore the process involved in the relationship between childhood victimization and later adult behavior, to examine the consequences of early childhood experiences and compare self-reports with the official records of criminal behavior and abuse neglect history. 700 respondents were interviewed, which required complex tracing and locating procedures. (*Client: Indiana University, Department of Criminal Justice.*)

1988 - 1989 PROJECT DIRECTOR: **Racial Variations in Glaucoma in Nursing Homes: Prevalence and Severity.** To determine the racial differences in the prevalence of glaucoma among a sample of nursing home patients. Developed complex sampling and rostering procedures to implement with the census of 30 nursing homes. Contacted and obtained the permission to perform study procedures in the nursing homes. Coordinated the sampling, interviewing and implementation of on-site comprehensive eye examinations. Developed procedures to determine the mental status of patients and obtaining consents from next-of-kin for those incapable of giving consent. Monitored budgets, developed computer tracking procedures and delivery of clean data (*Client: The Wilmer Institute, Johns Hopkins Hospital*).

1988 PROJECT DIRECTOR: **Study of the Practice Behaviors of Physicians Toward Diabetes in the State of Pennsylvania.** 600 physicians from the state of Pennsylvania were screened for eligibility and asked to complete a 30-minute telephone interview. The purpose of the study was to examine current practices of physicians in the treatment of diabetes and to determine areas of concern for which physicians would like further continuing education. (*Client: Pennsylvania State Department of Health.*)

1988 PROJECT DIRECTOR: **Quality of Life of Cataract Patients Study.** Development of methodology, questionnaires, manuals, forms, office and field procedures. Coordinated a difficult and complex methodology which included sampling of the universe of ophthalmologists in three metropolitan areas, screening ophthalmologists for eligibility and obtaining their compliance in referring patients into five distinct sub-groups. Three interview waves with respondents were completed in addition to obtaining an abstract of each patient's visual acuity and asking controls to have an additional acuity check during the field period. (*Client: Johns Hopkins University School of Hygiene and Public Health.*)

1988 PROJECT DIRECTOR: **Pilot Study of Alzheimer's Disease in Veterans of WWII Twins.** Coordinated the technical staff in usage of a CATI system to quickly screen respondents requiring further assessment of possible diagnosis of Alzheimer's disease. 440 twin pairs from the National Academy of Sciences' Registry were contacted to be interviewed. Extensive tracing and locating efforts were implemented. A brief screening interview was administered to determine those twins who were found to be at high risk for Alzheimer's Disease. (Client: *Duke University, Department of Psychiatry.*)

1987 - 1988 PROJECT DIRECTOR: **An Epidemiologic Study of Injuries in Firefighters.** Monitored field efforts for 800 telephone interviews with firefighters who had been recently injured on the job, and selected controls. Interviews had to be completed within 7 days of identification. The purpose of the study was to examine ways in which future injuries could be prevented or their severity reduced. (*Client: Department of Epidemiology, School of Hygiene and Public Health, Johns Hopkins University*).

1988 PROJECT DIRECTOR: **Detection and Management of Drug Side Effects in Elders.** Monitored field efforts and budgets. 1,100 patients from two HMO's in Baltimore were contacted by telephone six weeks after their most recent visit. The purpose of the study was to increase the clinician's awareness and communication with elderly patients concerning the management and detection of drug-related problems. (*Client: Johns Hopkins University, School of Hygiene and Public Health*).

1987 - 1989 PROJECT DIRECTOR: **Airways Obstruction and Smoking in Black and White Adults.** 9,000 brief telephone interviews with respondents who had volunteered for a lung screening program. The purpose of the study is to obtain past and current smoking histories with respondents. *(Client: Department of Epidemiology, Johns Hopkins University).*

1988 - 1989 PROJECT DIRECTOR: **Quality of Life of Elderly White Hypertensive Patients.** Development of a comprehensive questionnaire to ascertain patients subjective evaluation of changes in the quality of life during participation in a clinical trial. Developed the questionnaire in consultation with an advisory committee, oversaw the completion of pretesting procedures, prepared training manuals, trained clinic personnel for 25 sites to perform interviews. Oversaw completion of project, budgets and quality control procedures. *(Client: Glaxo Pharmaceuticals).*

1984 - 1988 PROJECT DIRECTOR: **Racial Variations in Glaucoma: Prevalence and Severity.** To determine the racial difference in the prevalence of glaucoma among a random household sample of the population. Developed complex procedures to sample, screen and interview 8,000 respondents. Over 5,000 respondents participated in an extensive eye examination at neighborhood clinics. Those who were found to have eye disease were requested to complete a definitive exam at the Wilmer Institute. Complex computer tracking procedures were required to monitor the fieldwork for 16 screening centers. Implemented procedures to monitor the complex logistics of the recruitment and clinic procedures. Developed innovative and motivational procedures to gain compliance of the selected population. *(Client: The Wilmer Institute, Johns Hopkins Hospital)*

1987 - 1988 PROJECT DIRECTOR: **Etiology of Tracheoesophageal Fistula/Esophageal Atresia.** Consulted on questionnaire design, developed instructional manuals, field, office and record keeping procedures and monitored field efforts. 600 cases and 900 controls were administered a 45-minute telephone interview about factors that may possibly be related to midline birth defects. *(Client: Department of Epidemiology, School of Hygiene and Public Health, Johns Hopkins University.)*

1986 - 1987 PROJECT DIRECTOR: **Study of Prenatal and Neonatal Factors in Childhood Strabismus.** Consultation on study design, questionnaire development, established operational procedures for abstracting opthalmic obstetric, and new-born records, wrote instructional and training manuals. Oversaw efforts of eliciting cooperation from 18 hospitals, clinics, physicians in private practice and record room personnel. Developed complex systems for this case/control study of a very specific population having multiple phases simultaneously in the field. *(Client: The Wilmer Eye Institute, Johns Hopkins Hospital.)*

1986 - 1987 PROJECT DIRECTOR: **Quality of Life of Black Hypertensive Patients.** Development of a questionnaire to ascertain the patient's subjective evaluation of the changes in the quality of life during participation in a clinical trial. Developed questionnaire in consultation with an advisory committee, oversaw completion of three separate pre-tests, presented implementation of the project to principal investigators from 12 clinic sites, trained clinic personnel from each site in interviewing, administration and quality control procedures. *(Client: Searle Pharmaceuticals.)*

1985 - 1987 PROJECT DIRECTOR: **Early Detection of Cervical Cancer Among Elderly Women.** Consulted with principal investigators on 2 years of this three year project. Included development of random digit dialing procedures using the Waksberg method, and sampling procedures for the physician interview phase. Pretests were conducted for both phases of the project. In Phase II, 1200 25 minute telephone interviews were completed utilizing R.D.D. In Phase III, 400 practicing physicians completed a 35-minute telephone interview concerning preventive/intervention health care used for women in their practices. *(Client: Johns Hopkins Univ, School of Hygiene and Public Health.)*

1987 - 1988 PROJECT DIRECTOR: **Impact of Mental Morbidity on the Nursing Home Experience.** Consulted on study and questionnaire design, developed instructional manuals, field, office and record keeping procedures and monitored field and data cleaning efforts. 550 baseline interviews were conducted with a responsible person for eligible elderly patients admitted to a group of nursing homes. A one year follow-up interview was also administered to learn about circumstances surrounding admissions/discharge at nursing homes. *(Client: Johns Hopkins University School of Hygiene and Public Health.)*

1983 - 1986 PRINCIPAL INVESTIGATOR: **A Prospective Study of the Frequency and Duration of Infant-Feeding Practices Among Primiparae.** A two-year study of 1200 Primiparae selected from Washington, DC hospitals with three follow-up interviews for each respondent. Required sampling from hospital logs, coordination between field staff working daily at hospitals and the SRA office. Consulting on study and questionnaire design, obtaining cooperation of health care providers, development of instructional manuals, field and office procedures, editing specifications and procedures, conduct of multiple trainings, monetary progress of study, prepared progress and final reports. Coordinated the effort required for computer tracking, quality control and data cleaning. *(Client: National Institute of Child and Human Development.)*

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1986 PROJECT DIRECTOR: **Health Care Finance Project.** Consulted on recruitment of the study population and development of a complex questionnaire to ascertain out of pocket expenses for families of children having chronic disabilities. The study design required multiple variations of the interview schedule as well as multiple requirements for interviewing care providers in residential settings. 715 telephone interviews of 45 minutes in length were completed within an 8-week field period. Complex data management and cleaning were required. (*Client: Albert Einstein, College of Medicine Yeshiva University.*)

1986 PROJECT DIRECTOR: **Study of the Needs of Cancer Patients in the Last Month of Life: As Reported by Their Significant Other.** Utilizing death certificates of persons who had recently died from cancer, a significant other was located and asked to complete a 40-minute telephone interview to report the needs of the cancer patient during the last month of life. Consulted on study design and questionnaire development, established operational procedures, tracing and locating significant others, wrote instructional and training manuals, trained interviewers, established a computerized record keeping system, monitored quality control and data cleaning efforts. (*Client: Department of Behavioral Science, The Pennsylvania State University College of Medicine, Hershey, PA.*)

1984 - 1987 PROJECT DIRECTOR: **Breast Cancer Screening and Detection Programs for the Cancer Control Program.** Consulted in development phases for the study including study design, questionnaire format, methodology, and field procedures. Complex sampling from the State Tumor Registry. Wrote training manual, trained field and office personnel; monitored complex data management; developed systems and reporting procedures. This study population included breast cancer patients and their female relatives who were interviewed pre and post intervention with a control group for comparison at a 3-year period. All respondents were also asked to take part in a follow-up intervention and education process. Developed and provided standardization procedures across 5 contract sites for interviewing and reporting. (*Client: Department of Behavioral Science, The Pennsylvania State University College of Medicine, Hershey, PA.*)

1985 PROJECT DIRECTOR: **Study of Abnormal Pregnancy Outcomes Among Spouses of Baltimore City Firefighters.** The purpose was to scientifically identify whether or not a problem of exposure to certain toxic or potentially toxic substances had a relationship to adverse reproductive events. 500 telephone interviews were administered to wives, partners or female paramedics in the Baltimore City Fire Department. Consulted on questionnaire design, forms and study procedures. Prepared training manuals, monitored technical staff and budgets. (*Client: Center for Occupational Health and Environmental Health, Johns Hopkins University*).

1984 - 1985 PROJECT DIRECTOR: **The Survey of Cancer Rehabilitation Related Problems.** Consulted with advisory committee, development and formatting of questionnaire, planning and implementing of multiple field processes. Developed complex tracking and receipt control procedures for recruiting respondents. Wrote training manuals, developed computerized report systems, monitored progress of study and prepared progress and final reports. This study was the first to utilize the Pennsylvania State Tumor Registry. The objective was to develop an effective statewide rehabilitation program for cancer patients and provide feedback on utilization of cancer registry. 2,100 interviews were conducted with patients, significant others, physicians, nurses, and social workers throughout the state of Pennsylvania. (*Client: Department of Behavioral Science, The Pennsylvania State University College of Medicine, Hershey, PA.*)

1984 - 1985 PROJECT DIRECTOR: **Family Planning Performance: Acceptance and Dropout.** A statewide study of women using the services of family planning clinics in 10 counties in the state of Maryland. Assisted in the development of the questionnaire and field procedures to coordinate the efforts of interviewers throughout the state. This study required multiple approaches due to the specific requirements of each county health officer. Wrote training manuals, trained field interviewers, monitored field efforts and analyzed budgets. (*Client: Department of Population Dynamics, Johns Hopkins University*)

1983 - 1985 PROJECT DIRECTOR: **Resource Use by Parenting and Pregnant Adolescents.** A two-year study to determine the resources use of various facilities by teenage mothers in the community. Consulted on questionnaire, designed study procedures and evaluated all aspects of the study during the field period. (*Client: Department of Pediatrics, School of Medicine, Johns Hopkins University*)

1984 PROJECT DIRECTOR: **A Case/Control Study of Port Allegany Asbestos Workers.** A psychosocial needs assessment study of workers in Port Allegany who were exposed to Asbestos at the Pittsburg Corning Plant. Consulted on study and questionnaire design, wrote training manual, developed field and office procedures, monitored progress and wrote final report. (*Client: Workers Institute of Safety and Health*)

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1984 PROJECT DIRECTOR: **Health Care Utilization of Anne Arundel County Residents.** To determine the health care utilization patterns and needs of Anne Arundel County residents. Developed random-digit-dialing procedures, field procedures and interview. Trained field interviewers and oversaw the completion of the project including analysis of 400 interviews within a 3-week time frame. (*Client: Arthur Anderson & Co.*)

1983 PROJECT DIRECTOR: **The Study of the Grief Reaction and Financial Burden on Spouses of Deceased Cancer Patients.** To obtain data on the grief reaction of spouses of cancer patients. Developed study design and formatted questionnaire. Supervised pre-test, wrote training manual and trained all personnel assigned to the study in handling this sensitive area of research. Developed computer sampling and reporting procedures. (*Client: Department of Behavioral Sciences, The Pennsylvania State University College of Medicine, Hershey, Pennsylvania.*)

1983 PROJECT DIRECTOR: **Women's Health Study.** A hospital sample to study the reproductive experiences of women in the Baltimore Metropolitan Area. Directed project, analyzed costs, performed all report procedures. Developed tracing procedures for difficult to locate respondents. (*Client: Department of Obstetrics & Gynecology, Johns Hopkins Hospital*)

1982 PROJECT DIRECTOR: **The Neighborhood Study.** To ascertain what factors make for positive residential atmosphere in neighborhoods. 1,700 interviews in a two-month period. Planned, directed and oversaw procedures as needed to complete fieldwork. Tabulated results and maintained close liaison with the contractor. Prepared final report. (*Client: Center for Metropolitan Planning and Research, Johns Hopkins University.*)

1982-1983 PROJECT COORDINATOR/SYSTEMS ANALYST: **Longitudinal Mental Health Study** (St. Louis, MO). To estimate the prevalence of mental disorders in various segments of the population. Preparation of site office, development of record keeping and reporting procedures, analysis of work flow and personnel needs; development of supervisory responsibilities, wrote training manuals and final report. Coordination of complex Electronic Data Processes procedures. (*Client: Department of Psychiatry, Washington University*)

1982-1983 PROJECT COORDINATOR/FIELD SUPERVISOR: **Consequences of Arrest for Marijuana Possession.** To study the consequences of arrest and trial on the lives of individuals who are charged and tried for various marijuana offenses. Monitor work flow, training, prepared budget reports, supervised 25 office and field staff requiring extensive tracing and locating procedures. Kept client informed on progress of field work, wrote final report. An 86% completion rate was achieved with a most transient population. (*Client: Department of Mental Hygiene, School of Hygiene and Public Health, Johns Hopkins University*)

1981-1982 PROJECT COORDINATOR/FIELD SUPERVISOR: **Secondary Prevention with Adult Patients in Primary Care Settings.** A complex, sensitive, 11-hour mental health interview with 800 clinic patients. Selected all personnel, organized training and prepared training manuals, supervised 15 office and field personnel. Developed all record keeping proce- dures and systems, prepared reports and statistics. Worked closely with client to schedule interviews in a short time frame. A 91% completion rate was achieved on this study. (*Client: Health Services Research and Development Center, Johns Hopkins University*)

1981-1982 PROJECT COORDINATOR/SYSTEM ANALYST: **Longitudinal Mental Health Survey.** To estimate the prevalence of mental disorders in a random sample of the population. 4,600 complicated interviews requiring extensive training. Assisted in training and development of field procedures, planned and implemented systems to increase efficiency of office and field work. Analyzed field difficulties and coordinated work effort. (*Client: Department of Mental Hygiene, School of Hygiene and Public Health, Johns Hopkins University*)

1981-1986 TRAINING COORDINATOR: Developed a **Basic Interviewing Techniques Training** for all interviewers new to the firm. Set operation objectives, wrote training materials and assessed the success of training.

INTERVIEWER

1980 FIELD INTERVIEWER: Several studies, including a **Pancreatic Cancer Study** and a **Mental Health Survey.**

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Consulting Experience

1986 Hershey Medical Center:
A Longitudinal Study of the Needs of Cancer Patients for the Duration of the Disease

1984 Pennsylvania State Department of Health: Division of Chronic Diseases
Breast Cancer Detection and Intervention Project Cervical Cancer Detection Project

Department of Environmental Health
Study of the Effects of Environmental Hazards on the Population of Centralia, PA

Bureau of Epidemiology
Hypertension Screening Follow-Up Study

Department of Health, Allentown, PA
Health Practices of Mothers Utilizing the Well-Baby Clinic

1983 Cancer Advisory Board of Pennsylvania.
Organized and conducted special workshops (focus groups) for cancer patients, families of cancer patients, physicians, nurses or social workers to determine the met and unmet needs of patients by the health care system. Wrote final report which was used to further plan for the needs of cancer patients.

Other Work Experience

1980 Johns Hopkins University, School of Hygiene and Public Health, Department of Mental Hygiene
Liaison between Survey Research Associates and Johns Hopkins University to oversee coordination of work on complex Longitudinal Mental Health Survey.

1979-1980 Several part time positions while completing Masters Degree:
Independent consulting - Stress management, Home Management of Handicapped Children, Step-Parenting, Tutorial Training

Baltimore County Circuit Court - Towson, MD.
Competency Screening to evaluate defendants pre-trial to determine competency and make recommendations to the court.

Center for Comprehensive Evaluation - Lutherville, MD.
Coordinator for the center, administered computerized psychological evaluations

Dundalk Community College - Dundalk, MD
Leader of a woman's development program. This included a large lecture class and several small discussion groups which focussed on the transitions in the lives of the women in the program.

Dundalk Family Crisis Center - Dundalk, MD.
Counselor for members of families requiring crisis intervention, primarily in the realm of abuse.

1975-1979 Juvenile Services Administration - Towson, MD.
Juvenile counselor - provided intake interviews, assessments, planned strategies for intervention, placement of juveniles, case management, probation and recommendations to Baltimore County Juvenile Court

Jemicy School, Owings Mills, MD.
Led discussion group for parents of dyslexic children. This group was both informational and for support purposes.

1967-1970 Baltimore County Public Schools, Baltimore, MD.

Cheltenham Public School, Cheltenham, PA. Teacher - Social Studies, Grades 7-9.

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Publications/Research

Ezrine, S., Kurinij, N., Shiono, P., and Rhoads, G. "Does Maternal Employment Affect Breast Feed?" *American Journal of Public Health*., September, 1989.

Ezrine, S., Houts, P., and Jones, M. "The Use of Surveys in Planning Statewide Services for Cancer Patients and Their Families - The Pennsylvania Experience." *AAPOR*, May, 1987.

Ezrine, Sandi. *A Primer on Dyslexia*. The Jemicy School, 1980.

Ezrine, Sandi (Ed.). *The Informant*. Newsletter for Survey Research Associates, Inc. 1982-Present.

Ezrine, Sandi. *Training and Troubleshooting Manual for Psyche Systems*. Prepared for Psyche Systems. Baltimore, MD. 1980.

Ezrine, Sandi. *Five Year Follow-Up of CINS Cases in Baltimore County.*

Tielsch, J., Sommer, A., Katz, J., and Ezrine, S. "Sociodemographic Risk Factors for Blindness and Visual Impairment. The Baltimore Eye Survey."

Member

REDACTED

Honors

Phi Alpha Theta Honor Society
Phi Kappa Delta Honor Society
Gewehr Award Nomination

CURRICULUM VITAE
PATRICIA MCGAHEY HENDERSON

Education

1973 M.A., Washington University, St. Louis, Missouri
1962 B.A., Washington University, St. Louis, Missouri

Work Experience

1982 - Survey Research Associates, Inc.
Delcrest Plaza Building, LL9
8420 Delmar Boulevard
St. Louis, Missouri 63124

EXECUTIVE DIRECTOR OF MIDWEST OPERATIONS

Managed more than 100 SRA office and field personnel hired to execute SRA projects in the midwest. Responsible for all data management systems, forms and reports for projects originating from St. Louis. Responsible for liaison work with researchers in research institutions, private companies, and local and state agencies located in the midwest.

1987-1990 STUDY MANAGER: **Case/Control Study of Residential Exposure to Radon.** Responsible for overseeing the ascertainment of the case sample, the selection of the control sample, and the field implementation of the study. Responsible for supervising the Registry Coordinator in the coordination of case ascertainment/abstracting with the Missouri Cancer Registry. Also responsible for supervision of data collection efforts in screening the control sample, interviewing cases and controls, and the installation and collection of radon dosimeters. Supervised the Registry Coordinator, field clerks, and telephone interviewers. Responsible for establishing working relationships with registry personnel, local government officials, health care facilities, and private practitioners. Obtained clearances from clinicians or institutional boards when required. Prior to initiation of the study, helped to develop a formal plan, outlining the methods, procedures, and options to be utilized for identifying, approaching, and negotiating with relevant individuals and organizations for the development of final study protocol. This project was a three-year, multi-site, surveillance study of 850 women and close to 3,000 households in the state of Missouri. Cases were referred from those non-smoking women who were recently diagnosed with lung cancer through the Missouri Cancer Registry. Controls were obtained from DMV and HCFA tapes and screened for eligibility. Current and former residences of respondents were contacted to complete an on-site construction survey and radon dosimeters were placed in each respondent's household. SRA was responsible for providing quarterly surveillance of respondents. Radon dosimeters were retrieved one year later and sent for laboratory analysis. Data for all phases of the project were integrated for analysis. (*Client: National Cancer Institute*)

1989-1990 FIELD DIRECTOR: **Patterns of Alcoholism in Subsamples of Homeless Men.** Assisted the Project Director in the preparation of extensive training materials and conduct of a one week training on complex DIS-III-R based interview. Coordinated the pretest of the interview in shelters for the homeless. Was responsible for coordinating the sampling of homeless men from shelter, day center, and street populations in St. Louis. Coordinated daily activities of study with shelter and day centers for the homeless and Washington University. The study involved populations of homeless men from shelters, day centers, and the streets. A DIS-III-R interview was conducted with each selected respondent to determine the frequency and type of psychiatric disorder, focusing on drug and alcohol dependence. (*Client: Washington University*)

1989 PROJECT DIRECTOR: **Health and Adjustment in Young Adults.** Directed the pretest and recruited field interviewers for this study of young adults in Detroit, Michigan. Responsible for monitoring data collection activities for the DIS-III-R based study of members of the Health Alliance Plan in Detroit, Michigan. Assisted in the development of training materials and during the week-long training of interviewers. This study focused on young adults between the ages of 20 and 30; exploring how psychological distress affects physical health. Respondents from the membership lists of the Health Alliance Plan in Detroit. (*Client: Henry Ford Hospital*)

1987 - 1992 FIELD DIRECTOR: **A Prospective Analysis of the Causes and Risk Factors of Falls.** Assisted Project Director in development of extensive training materials and conduct of 1 week training on complex in-person questionnaire and administration of physical and mental assessments. Responsible for managing all data collection activities in the St. Louis Office and all interviewers. Coordinated various aspects of study with OASIS and Jewish Hospital of St. Louis. This was a longitudinal study conducted to assess the causes and prevention of hip fractures in the elderly. The study involved a large data set of 1,350 respondents with a follow-up interview 1 year from the baseline interview and monthly surveillance for 5 years. Respondents were instructed in the use of monthly fall reporting postcards; nonresponders were telephoned monthly. Respondents for the study were randomly selected from the membership of the St. Louis OASIS, an organization for independent-living adults over age 60 and community controls. (*Client: St. Louis Jewish Hospital and the National Institute of Aging*)

1987 - 1991 FIELD DIRECTOR: **Evaluation Study of the National AIDS Health Services Demonstration Project.** Responsible for monitoring all data collection activities. Initiated SRA contact with all program clinic sites and collaborated with the director of each program to establish lines of communication between SRA staff and program staff and to set up procedures for accomplishing the evaluation study's objectives at each site. Recruited and managed office personnel, supervised the interviewers and medical record abstractors. Responsible for assuring that data collection complied with all established procedures and timelines. Communicated to the Project Director any difficulties encountered in implementing the procedures, documented difficulties, and suggested alterations for avoiding and/or overcoming them. This was a multi-site, three-year study involving a large data set: 1,240 in-person interviews and 1,400 medical record abstracts. The objectives of the study were to examine the pattern of service use and to evaluate the case management of AIDS patients in nine cities through record abstracting and interviewing service recipients on the quality of services received. Respondents were given an intake interview at each clinic site involving very sensitive subject matter. Respondents were individuals diagnosed with AIDS, HIV or ARC using Robert Wood Johnson funded services. (*Client: Robert Wood Johnson Foundation and Brown University*)

1988 PROJECT COORDINATOR: **Quality of Life of Cataract Patients.** Coordinated data collection activities in three U.S. sites: Baltimore, St. Louis and San Diego. Supervised site coordinators and coordinated compliance efforts of ophthalmologists in three metropolitan areas in the referral of patients into five distinct subgroups. This was a national surveillance survey conducted for The Johns Hopkins University under joint contract with the American Society of Cataract and Refractive Surgery (ASCRS) and the Outpatient Ophthalmic Surgery Society (OOSS) to complete an objective assessment of the outcome of the intraocular lens implantation. Interviews for the study were arranged through the offices of approximately fifteen participating physicians in each of three study sites. The large respondent population was composed of elderly individuals who completed an in-person pre-operative baseline interview, a two-month post-operative interview. The large data set of 1,000 individuals consisted of both cases and controls. (*Client: The Johns Hopkins University*)

1986 - 1987 PERSONNEL DIRECTOR: **Dalkon Shield Litigation Project in Richmond, Virginia.** Responsible for recruiting over 200 employees necessary to complete all of the tasks involved. Held informational sessions to recruit applicants, personally interviewed applicants and managed the evaluative and selection efforts. Maintained personnel files and consulted with project director in Baltimore about personnel matters. This intensive short-term project was conducted for the Bankruptcy Court to gather data to estimate damages and test procedures for resolution of claims. (*Client: U.S. Bankruptcy Court*)

1986 - 1988 FIELD DIRECTOR: **Longitudinal Study of Adolescents and Their Children.** Directed field and quality control efforts. About 500 teenage mothers in three cities nationwide were identified to take part in this three-year longitudinal study. Medical record abstracts were obtained for the babies from 19 different clinics. (*Client: Department of Health and Human Services and Washington University*)

1986 FIELD DIRECTOR: **Access to Medical Care of Food Bank Recipients Study.** Recruited 43 agencies who distributed food to the needy to participate in this national study for the Robert Wood Johnson Foundation. Made all arrangements for data collection with the directors of the food bank centers. Hired interviewers and supervised the data collection activities in the 43 distribution centers (soup kitchens and bread lines). Did all the trouble-shooting for this complex study of health care needs among disadvantaged and often transient respondents. (*Client: Robert Wood Johnson Foundation and UCLA*)

1984 - 1986 FIELD DIRECTOR: **Health in Teens Study (HITS) Waves I and II.** Responsible for convincing the director at each of the 42 different clinics in ten cities nationwide to participate in this longitudinal evaluative study of their programs for high risk adolescents as funded by the Robert Wood Johnson Foundation. Established rapport with staff in each clinic as well as unique procedures to be used in data collection in each clinic. Made arrangements for and assisted with training. Developed all field schedules. Supervised 32 interviewers in 10 cities. Monitored quality control operations. Generated weekly progress reports. Met regularly with Washington University staff members to update them on field progress and problems. Coordinated sampling and data collection efforts for the longitudinal study of 3000 high-risk adolescents, including 2 DIS-based interviews and a medical record review of each respondent. This longitudinal study evaluated the effectiveness of health service networks funded to provide comprehensive and coordinated services to high risk adolescents. (*Client: Robert Wood Johnson Foundation and Washington University*)

1982 - 1984 SITE OFFICE DIRECTOR AND FIELD MANAGER: **Health Effects of Environmental Hazards Study.** Manager for study of the effects of environmental health hazards on the community. Responsible for identifying a sample of St. Louis communities affected by various health hazards. Compiled an historical account of the chronology of the spread of dioxin in the St. Louis area. Directed interviewers, editors and other office personnel involved with the study. Assisted in development of training manuals and procedures. Analyzed costs and wrote interim progress reports. Respondents were selected from populations previously interviewed in the St. Louis E.C.A. Study, living in households in known disaster areas and from households in matched control neighborhoods in St. Louis and surrounding counties. (*Client: Washington University and NIMH*)

Patricia M. Henderson

1982 - 1983 SITE OFFICE DIRECTOR: St. Louis Epidemiological Catchment Area Study (ECA), Wave II. Managed the St. Louis Office of Survey Research Associates, consisting of 3-4 supervisors of interviewers, an office manager, a quality control supervisor, 5 editors, an office clerk, and clerical helpers. Directed all data collection activities for the last two phases of the longitudinal Epidemiological Catchment Area (ECA) Study for Washington University's School of Medicine, including the Six-month Phone Follow-up Interview and the Wave II Re-interview of the 3500 respondents interviewed during Wave I. Was respon-sible for recruiting and maintaining cooperative effort with directors of all institutions and group quarters included in the Institutional Sample and Group Quarter Sample. Coordinated trainings and informational debriefings for office and field staff; prepared interim reports to the staff of the Washington University's School of Medicine and the SRA staff in Baltimore. The St. Louis ECA Studies (Wave I and Wave II) were designed to estimate prevalence of specific mental disorders and studied factors associated with the development and continuance of these disorders. Relationships between psychiatric disorders and utilization of health care facilities were analyzed. (*Client: Washington University and NIMH*)

National Opinion Research Center
University of Chicago
Chicago, Illinois

1981-1982 FIELD MANAGER: St. Louis ECA, Wave I, NORC St. Louis Site Office. Managed all field data collection activities in the St. Louis Site Office for Wave I of the St. Louis Epidemiological Catchment Area (ECA) Study for Washington University's School of Medicine. Recruited, interviewed, hired, and supervised the field office staff consisting of 3-4 field supervisors, 50-80 field interviewers and a logger. Directed sampling effort and all data collection efforts for the Institutional Sample and the Group Quarters Sample. Was responsible for preparing weekly cost and production reports to NORC at the University of Chicago. Met regularly with Washington University staff members to discuss problems and update them about the progress of the fieldwork.

Research Triangle Institute
Research Triangle Park, North Carolina

1979-1980 DISTRICT SUPERVISOR: National Assessment of Educational Progress. Supervised all sampling and data collection activities for the National Assessment of Educational Progress (NAEP) in the three-state area of Missouri, Arkansas, and Southern Illinois. Organized informational meetings for over 100 schools sampled each year to gain cooperation of school officials. Coordinated assessment with school administrators. Recruited, hired, and trained the interviewers. Was responsible for meeting the requests of the school officials and maintaining the cooperative spirit.

Hospital Research Associates
Fanwood, New Jersey

1977 - 1982 CONSULTANT: Supervised marketing research data collection activities and auditing activities in St. Louis area hospitals. Responsible for recruiting hospitals to participate in market research studies. Converted refusals and validated supervisors interviews and audits.

AKG Marketing Research Services
St. Louis, Missouri

1974 - 1979 SUPERVISOR, EVALUATOR, INTERVIEWER

Planned and supervised data collection activities. Worked on a free-lance basis on numerous evaluative studies and opinion and marketing research projects. Moderated group sessions; analyzed data and developed reports. Specific projects:

Longitudinal Evaluative Study of the Veterans Adminis-tration's Drug Addiction Treatment Program (*MACRO, Silver Springs, MD*): Supervised and participated in the field work for the St. Louis portion of a national evaluation study of the V.A.'a drug addiction treatment program. The study lasted for two nine-month periods in 1973 and 1976.

Study of HUD's Section 8 Housing Program (*Abt Associates, Cambridge, MA*): Supervised all sampling and data collection activities in St. Louis for Abt Associates' study of HUD's Section 8 Housing Program; hired, trained and supervised sampling personnel and interviewers. Was responsible for recruiting Section 8 offices to participate and maintained cooperative spirit among those being evaluated.

Study of Nutrition Among the Elderly for the Department of Health, Education and Welfare (*Opinion Research Center, Princeton, NJ*): Supervised a two-month study for ORC concerning nutrition among the elderly for HEW and several like studies concerning school breakfast and lunch programs. Recruited schools and programs to participate and was responsible for compliance.

Study about the Needs of Teenage Runaways for the Department of Health, Education and Welfare (*Opinion Research Center, Princeton, NJ*): Supervised the field work and interviewed respondents during a study concerning the needs of teenage runaways for HEW by ORC. Responsible for sampling at centers for teenage runaways. Recruited centers to participate in study and was responsible for on-going working relationship between ORC and centers for runaways.

Study of Vocational Rehabilitation Program for the Department of Health, Education and Welfare (*Opinion Research Center, Princeton, NJ*): Supervised the field work for a six-month study by ORC of HEW's Vocational Rehabilitation Programs in St. Louis. Responsible for on-going cooperation of programs and maintaining that compliance.

Study about the Employability of Former Cancer Patients (*National Cancer Institute*): Supervised several interviewers and personally completed 50% of the interviews, including presidents and personnel managers of large corporations throughout the Midwest.

Study of Customer Needs (*St. Louis County Bank*) Supervised sixteen interviewer during a study of the bank's services. Coordinated approximately 1000 bank transactions during the intensive one-month study.

Customer Needs Study (*Pope's Cafeterias*): Supervised data collection and wrote evaluative reports for management of the chain of cafeterias about customer needs.

Television Commercials, Kroger Foods (*Campbell-Mithun, Chicago, IL*): Recruited shoppers to appear in television commercials and interviewed them on camera. The commercials were produced over a six-month period in St. Louis, Atlanta, Indianapolis, Memphis, and Nashville, among other cities.

Focus Groups, Sears Television Commercials (**Sears, Roebuck and Co., Chicago, IL**): Moderated Sears focus group sessions to test the appeal of television advertising. About 100 respondents attended each of 45 focus groups which were held three nights per month for fifteen months at Channel 9, St. Louis, MO.

Supervised numerous marketing research projects, both long-term and short-term, for St. Louis and national companies. Responsible for recruiting, training, and supervising interviewers and for the supervision of quality control procedures. Marketing research clients included such companies as: IBM, First National Bank of St. Louis, Six Flags, General Foods, Hershey Chocolates, McDonald's, Burger Chef, Ralston Purina, Toyota, Porsche-Audi, Southwestern Bell Telephone, Sears, Carling Brewing Company, U. S. Navy, Zantigo, Merle Norman, G.T.E., and Blue Cross Insurance.

1962-1973 Teacher,
St. Louis County, Missouri

Taught in the elementary grades, with an emphasis on language arts activities and fine arts.

Professional Presentations

Paper presented at the November, 1985 meeting of the American Public Health Association. Fischbach, Ruth and Patricia Henderson (Washington University School of Medicine). "Exposure to Dioxin and Radionuclides in the Public Water Supply: Contrast in Community Awareness."

CURRICULUM VITAE

JOAN R. HUBER

Education

1955 A.S., Endicott College, Beverly, Massachusetts

Work Experience

1982 - Survey Research Associates, Inc.
Delcrest Plaza Building, LL9
8420 Delmar Boulevard
St. Louis, Missouri 63124

1987-1990 FIELD SUPERVISOR: **Case/Control Study of Residential Exposure to Radon.** Responsible for coordinating case ascertainment/abstracting with the Missouri Cancer Registry. Supervised data collection efforts in screening the control sample, inter- viewing cases and controls, and the installation and collection of radon dosimeters. Served as the supervisor of the field clerks and telephone interviewers. Was respon- sible for day to day contact necessary to implement field work with lung cancer patients and their next-of-kin, controls, landlords, institutions, administrators, physicians, lawyers, and Missouri Department of Health staff. This project was a three year, multi-site, surveillance study of 850 elderly women in the state of Missouri. Cases were referred from those non-smoking women who were recently diagnosed with lung cancer through the Missouri Cancer Registry. Controls were obtained from DMV and HCFA tapes and screened for eligibility. Current and former residences of respondents were contacted to complete an on-site construction survey and radon dosimeters were placed in each respondent's household. SRA was responsible for providing quarterly surveillance of respondents. Radon dosimeters were retrieved one year later and sent for laboratory analysis. Data for all phases of the project were integrated for analysis. (*Client: National Cancer Institute*)

1989 FIELD SUPERVISOR: **Health Adjustment in Young Adults.** Assisted in the recruiting of field interviewers and pretesting the interview. Managed data collection for the DIS-III-R based study of members of the Health Alliance Plan in Detroit, Michigan. Assisted during the weeklong training of interviewers. This study focused on young adults between the ages of 20 and 30 exploring how psychological distress affects physical health. Respondents for the study were randomly selected from the membership list of Health Alliance Plan in Detroit. (*Client: Henry Ford Hospital*)

1989 - 1992 FIELD SUPERVISOR: **A Prospective Analysis of the Cases and Risk Factors of Falls.** Assisted Project Director in the one week training on complex in-person questionnaire and administration of physical and mental assessments. Responsible for managing all surveillance activities each month with 1350 respondents, including monthly postcards and/or phone calls. This was a longitudinal study conducted to assess the causes and prevention of hip fractures in the elderly. The study involved a large data set of 1,350 respondents with a follow-up interview one year from the baseline interview and monthly surveillance for five years. Respondents were instructed in the use of monthly fall reporting postcards; non-responders were telephoned monthly. Respondents for the study were randomly selected from the membership of the St. Louis OASIS, an organization for independent living adults over aged 60 and community controls. (*Client: St. Louis Jewish Hospital and the National Institute of Aging*)

1987 - 1989 FIELD SUPERVISOR: **Quality of Life of Cataract Patients.** Supervised data collection activities in St. Louis and San Diego. Obtained compliance of ophthalmologists in two metropolitan areas in the referral of patients into five distinct subgroups. This was a national surveillance survey conducted for The Johns Hopkins University under joint contract with the American Society of Cataract and Refractive Surgery (ASCRS) and the Outpatient Ophthalmic Surgery Society (OOSS) to complete an objective assessment of the outcome of the intraocular lens implantation. Interviews for the study were arranged through the offices of approximately fifteen participating physicians in each of three study sites. The large respondent population was composed of elderly individuals who completed an in-person pre-operative baseline interview, a two-month post-operative interview. The large data set of 1,000 individuals consisted of both cases and controls. (*Client: The Johns Hopkins University*)

1984 - 1986 ASSISTANT SUPERVISOR: **Health in Teens Study (HITS) Waves I and II.** Assisted in the recruitment and hiring of the over 50 member staff necessary to implement data collection, supervision and quality control. Assisted Washington University staff with the development of the complex interviews used in both waves of this sensitive study. Assisted the Project Director in the development of training materials. Was an integral part of the SRA/Washington University team to train interviewers and editors for Waves I and II. Trained interviewers who were unable to attend the training in St. Louis. Coordinated interviewer observations, reviewed taped interviews, and was responsible for the quality of the interviewing and the retraining of those interviewers who needed assistance with this difficult interviewing instrument. Assisted with the supervision of national field operations and office management. Supervised the St. Louis team reviewing medical records of respondents and helped troubleshoot those teams in other cities. This longitudinal study evaluated the effectiveness of health service networks funded to provide comprehensive and coordinated services to high risk adolescents.

1989 - 1990 TRAINER: **Patterns of Alcoholism in Subsamples of Homeless Men.** Assisted the Project Director in the extensive training for interviewers on the complex DIS-III-R based interview. Responsible for retraining field staff to strengthen interviewing skills in the administration of the DIS-III-R. The study involved populations of homeless men from shelters, day centers, and the streets. A DIS-III-R interview was conducted with each selected respondent to determine the frequency and type of psychiatric disorder, focusing on drug and alcohol dependence. (*Client: Washington University*)

1988 - 1991 TRAINER: **Evaluation Study of the National AIDS Health Services Demonstration Project.** Assisted with the recruitment and supervision of the interviewers and medical record abstractors. Assisted in the week-long training of field interviewers and abstractors and served as the Brief Cognitive Screener Liaison between Brown University and field personnel. This was a multi-site, three year study involving a large data set: 1,240 in-person interviews and 1,400 medical record abstracts. The objectives of the study were to examine the pattern of service use and to evaluate the case management of service recipients on the quality of services received. Respondents were given an intake interview at each clinic site involving very sensitive subject matter. Respondents in three cities were given a Brief Cognitive Screener developed by Brown University researchers. Respondents were individuals diagnosed with AIDS or HIV/ARC in nine cities nationwide who had used the Robert Wood Johnson funded services. (*Client: Robert Wood Johnson Foundation and Brown University*)

1986 - 1987 RECRUITMENT SPECIALIST: **Dalkon Shield Litigation Project in Richmond, Virginia.** Assisted in the recruitment of over 200 employees necessary to complete all of the tasks involved in the project; organized informational sessions to recruit applicants; checked all references; assisted in the evaluation of all applicants and in the final selection process. This intensive short-term project was conducted for the Bankruptcy Court to gather data to estimate damages and test procedures for resolution of Dalkon Shield claims.

1982 - 1984 FIELD INTERVIEWER: **Health Effects of Environmental Hazards Study.** Interviewed for study of the effects of environmental health hazards on the community. Assisted in the supervision of less experienced interviewers, editors, and other office personnel involved with the study. Pretested this complex interview and assisted in the development of training manuals and procedures. The study focused on the emotional and mental health consequences of disaster. Respondents were selected from populations previously interviewed in the St. Louis Health Study, living in households in known disaster areas and from households in matched control neighborhoods in St. Louis and surrounding counties. @H4 = 1982 - 1983

FIELD INTERVIEWER: **St. Louis Epidemiological Catchment Area Study (ECA), Wave II.** Participated in data collection activities for the last two phases of the longitudinal Epidemiological Catchment Area (ECA) Study for Washington University's School of Medicine, including the Six-month Follow-up Interview and the Wave II Re-interview of the 3,500 respondents interviewed during Wave I. Established and maintained ongoing cooperative effort with directors of all institutions and group quarters included in the Institutional Sample and Group Quarter Sample. Debriefed Washington University School of Medicine research team about various field problems on a regular basis. The St. Louis ECA Studies (Wave I and Wave II) were designed to estimate prevalence of specific mental disorders and studied factors associated with the development and continuance of these disorders. Relationships between psychiatric disorders and utilization of health care facilities were analyzed.

National Opinion Research Center
University of Chicago
Chicago, Illinois

1979 - 1987 FIELD INTERVIEWER: National Longitudinal Study for the Department of Labor. Interviewed respondents in the midwest for this sensitive longitudinal study of young adults. Performed cognitive measurements with the biological children of female respondents during Wave 8 of NLS.

1981 - 1982 FIELD INTERVIEWER: St. Louis ECA, Wave I, NORC St. Louis Site Office. Participated in field data collection activities from the St. Louis Site Office for Wave I of the St. Louis Epidemiological Catchment Area (ECA) Study for Washington University's School of Medicine. Participated in sampling effort and all data collection efforts for the Institutional Sample and the Group Quarters Sample.

U. S. Department of Commerce
Bureau of the Census
Kansas City, Kansas

1971 - 1988 FIELD INTERVIEWER: Current Business Report and Consumer Expenditure Survey.

1981 FIELD INTERVIEWER: National Health and Leisure Time Survey.

1979 - 1981 FIELD INTERVIEWER: National Housing Survey.

1974 FIELD INTERVIEWER: National Crime Survey.

Community Service

Children's Hematology Research Effort (CURE)
St. Louis Children's Hospital
St. Louis, Missouri

1988 - Served on the Executive Board member for nine years. Served on the coordination team for ongoing fund-raising efforts. Was active in the establishment of the St. Louis Ronald McDonald House serving Washington University Hospitals and St. Louis University Hospitals.

CURRICULUM VITAE

O. Susan Butler

Education

1982M.A., University of Missouri-St. Louis; Sociology
1979B.S., Pennsylvania State University, Middletown, Pennsylvania; Social Science

Work Experience

1987 - Survey Research Associates, Inc.
Delcrest Plaza Building, LL9
8420 Delmar Boulevard
St. Louis, Missouri 63124

QUALITY CONTROL DIRECTOR/DATA MANAGER

Responsible for the quality of raw data collected by the St. Louis SRA midwest office. Works closely with principal investigators in developing the instrument specifications for project manuals and in formulation and maintenance of editing and coding decisions throughout all projects to insure quality and consistency. Trains and supervises the editing/coding staff, responsible for the implementation of manual editing and for code development. Trains and supervises computer editing staff, responsible for the development of computer editing programs and for implementation of electronic cleaning of the data. Collaborates with computer programmer and supervises data entry personnel. Assists project directors in a variety of areas including questionnaire design and project implementation.

1989-1992	**Substance Abuse and Risk for AIDS.** (*Client: Washington University. Funding source: National Institute of Drug Abuse.*)
1989 - 1990	**Patterns of Alcoholism in Subsamples of Homeless Men and Women.** (*Client: Washington University. Funding source: National Institute of Alcoholism and Alcohol Abuse.*
1989	**Follow-Up to the Evaluation Study of the Program to Consolidate Services for High Risk Young People.** (Client: Washington University. Funding source: National Institute of Mental Health.)
1989	**Childhood Victimization and Violent Behavior Study.** *(Client: Indiana University. Funding source: National Institute of Justice.)*
1989	**Health and Adjustment in Young Adults.** *(Client: Henry Ford Hospital. Funding agency: National Institute of Mental Health.)*
1987-1992	**A Prospective Analysis of the Causes and Risk Factors of Falls.** *(Client: St. Louis Jewish Hospital and Washington University. Funding source: National Institute of Aging.)*
1987-1991	**Evaluation Study of the National AIDS Health Services Demonstration Project.** *(Client: Brown University. Funding sources: Robert Wood Johnson Foundation and National Center of Health Statistics Research.)*
1987-1990	**Case/Control of Residential Exposure to Radon.** *(Client National Cancer Institute and Missouri Department of Health.)*
1988	**Quality of Life of Cataract Patients.** *(Client: The Johns Hopkins University.)*

1987 - Maryville College
St. Louis, Missouri 63141

Adjunct Faculty Member
Teaches Statistical Methods and Sociology.

1987 Fact Finders, Inc.
11960 Westline Industrial Drive
St. Louis, Missouri 63146

Project Manager - Feasibility Study on Proposed Washington University Cancer Center.
Analyzed data and contributed to report writing on market study to assess anticipated use of the proposed cancer center.

Project Manager - Lincoln Customer Service Survey.
Analyzed data and wrote report for mail customer service survey for an automotive equipment manufacturer.

1983-1987 Washington University
St. Louis, Missouri 63130

1986-1987 **Assistant Director of Development.** Directed a variety of Engineering Annual Fund Programs including the Phonathon Program, Century Club (giving club) Membership Program, Parents Fund, Young Alumni activities, Alumni Achievement Awards Program and special cultivation events.

Prepared proposals to corporate and private foundations for scholarship support, facilities improvements and other needs of the School. Planned and implemented the development program for the new School of Technology and Information Management, affiliated with the School of Engineering.

1984-1986 **Manager of Contracts and Grants.** Managed sponsored projects proposal submission. Negotiated terms and conditions of grants, contracts, and subagreements. Administered post-award activities. Compiled and analyzed data on University research activity; prepared annual and special reports on such activity. Supervised two grant and contract coordinators (entry level professionals). Administered the National Institute of Health Biomedical Research Support Grant Program for the University's main campus. Monitored and maintained all rules, regulations, and policies of both the granting agencies and the University for proper proposal submission and administration.

1983-1984 **Sponsored Projects Specialist.** Managed fund searching activities for faculty support, advised faculty members in grant application and proposal preparation, acted as liaison between the University and various funding agencies in fulfilling pre-award requirements, initiated and edited monthly publication providing vital research and topical information to 1,500 faculty members and administrative personnel, disseminated contract and grant opportunity information to appropriate research audiences, and maintained a computer-based information system for sponsored research development.

1982-1983 Big Brothers/Big Sisters of Greater St. Louis, Inc.
St. Louis, Missouri

Recruitment Coordinator - Managed agency public relations, coordinated special events, delivered public addresses, planned and implemented recruitment drives, organized several successful fund raising events, and managed a 40-client caseload.

1980-1982 University of Missouri - St. Louis
St. Louis, Missouri

Teaching Assistant - Taught Quantitative Techniques in Sociology and Introduction to Sociology

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1981 Public Systems Evaluation, Inc.
Boston, Massachusetts 02139

Research Consultant - Collected and compiled data for a crime deterrence experiment in metropolitan St. Louis.

1978-1980 Developmental Disabilities Advocacy Network, Inc.
Harrisburg, Pennsylvania 17110

Senior Regional Coordinator - Organized and provided technical assistance to community advocacy groups. Coordinated a network of volunteers throughout a fifteen county area. Negotiated with service providers, employers, and school administrators to access client's legal rights. Planned conferences on advocacy and legal issues affecting developmentally disabled persons, and conducted public speaking engagements.

Professional Affiliations

REDACTED
REDACTED

CURRICULUM VITAE

Christine Louise Thompson

Education

1972 B.S., Towson State University; Psychology and General Science

Areas of Special Competency

Applications Programming: Programming for a wide variety of applications. Experienced in all stages of program development from design to implementation, with an emphasis on systems design and statistical applications. Writes programs to develop front-end procedures for sampling, data collection and receipt control systems. Extensive programming experience with CATI systems. Conducts statistical analysis to produce preliminary and final reports.

Programming Languages: PL1 (5 years), FORTRAN (10 years).

Statistical Packages: SAS (5 years); SPSS (5 years); SPSS-X (2 years); BMDP (6 years).

Hardware: IBM 360/370 with OS/MUS (5 years); DEC VAX 11 series, model 780 with VMS (4 years); PDP11; SEL 810; and Data General's Eclipse.

Related Experience: Wylber text editing system (10 years); used National Computer Center (NCC) in North Carolina.

Work Experience

1987 Survey Research Associates, Inc.
6115 Falls Road
Baltimore, Maryland 21218

DATA PROCESSING DIRECTOR

Responsible for working with project and client staff to design, develop, and implement systems for all contracts. Develops programs for sample selection, statistical analysis and reporting, coordinates computer deliverables with each client's needs, and creates error checking programs as part of the internal quality control procedures for all computer operations. Coordinates with the Data Manager in the administration of all data processing tasks, including the planning, allocation, and supervision of workload.

1980-1987 Westat, Inc.
Bethesda, Maryland

SYSTEMS ANALYST

Responsible for the design, development, and implementation of systems for sampling, data analysis, receipt and control, and statistical reporting. Programmed CATI systems to drive interviews and produce field analysis reports. Created preliminary and final data tapes in accordance with contract specifications.

1974-1980 National Institute of Mental Health, NIH
Lab of Psychology and Psychopathology
Bethesda, Maryland

RESEARCH PSYCHOLOGIST

Responsible for basic research and statistical applications. Designed, developed, and implemented psycho-physiological research. Collected, edited, and reformatted data for analytic purposes. Employed parametric and nonparametric statistical techniques to analyze data for published reports.

Relevant Experience

Electric Utility Workers Study for the Virginia Power Company. Designed and supervised the programming of an interactive database system to collect abstracted employment histories of electric utility workers. Supervised the development of computerized data coding and job reclassification systems.

Survey of Physicians' Practice Behaviors Related to the Prevention of Lung Diseases. For this national survey of physicians, wrote the tracking system and restructured collected interview data. Collaborated with an analysis team from the Johns Hopkins University to produce all analytic statistical tables and to write and edit monitoring panel and final reports. The survey was conducted for the National Heart, Lung, and Blood Institute.

Residential Exposure to Radon. Designed and developed programs for sample selection and survey tracking on this case/contro of nonsmoking females who contracted lung cancer while residing in the state of Missouri for the last 25 years. This study was conducted for the National Cancer Institute.

National Medical Expenditure Survey (NMES). Using the Cheshire CATI system wrote the main programs and subroutines to drive the next of kin interviews for the Personal History Questionnaire (PHQ). The interview recorded information about medical and housing histories for current residents of nursing homes and homes for the mentally retarded. These programs, which approximately 35 inter-viewers could use simultaneously, scheduled cases, rescheduled appointments and aided interviewers in finalizing cases.

Army Communications Objectives Measurements Survey (ACOMS). For this national survey wrote and executed programs involved in sample selection for telephone interviewing using random digit dialing procedures. The procedures were also applied to a series of telephone exchanges which demographically contained high proportions of the national Hispanic population. Designed and wrote programs to aid in the monthly identification of residential households as well as the monthly generation of the sample telephone numbers. For this CATI study, developed the field reporting system for interviewer level and project level response rates.

Survey to Assess the Prevalence, Attitudes, Knowledge and Beliefs About Smoking Behavior Among Adult and Teenage Populations. Wrote and executed programs to create a national sample including Alaska and Hawaii for telephone interviewing using random digit dialing procedures. Developed for this CATI study the field reporting systems for response rates. Calculated weights and produced tables comparing charateristics between this sample and the ACOMS sample.

Survey of Industrial Generators of Non-hazardous Waste. As a statistical programmer, developed the field reporting system for response rates and a program that identified targeted industries. This system utilized and interacted with CATI files and structures. This EPA project will estimate the numbers of industrial landfalls, surface impoundments, and land application units engaged in the management of non-hazardous wastes.

Nationwide Household Exposure Survey of Products Containing Six Chlorocarbons. This EPA Survey is determining the frequency and duration of consumer exposure to household and automotive products containing chlorocarbon compounds. As a statistical programmer, developed the sample selection for random digit dialing telephone surveys.

Survey of Leaking Underground Storage Tanks. Created a national county data tape with summary characteristics and sampling inforproject conducted for the Environmental Protection Agency. Also drew the study sample; computed tabulations, weights and variances; created files for the receipt control system; and generated mailing labels.

RCRA Hazardous Waste Survey. Developed program to recode and update information to the general and incinerator questionnaires on this major survey of hazardous waste generators and management facilities conducted for the Environmental Protection Agency. Also developed additional analytic edits and tables for the data files and created a data base for EPA to use to access information about hazardous wastes.

Survey of TVA Commercial and Industrial Customers. Wrote programs to create primary and replicate weights and to calculate variance estimates and produce tables for the final report, for this survey conducted for the Tennessee Valley Authority.

Evaluation of NMCUES Data Collection and Processing Procedures. Wrote programs to create replicate weights using the jackknife technique. Also wrote programs to run national estimates and variances. By reducing the original information on the NMCUES Public Use Tapes from a multiple record per person format to a single record per person format, was able to create a series of data sets that described the individual user's medical utilization for 1980. Wrote programs in PL/1 to calculate tables for the final report, and assisted in writing and editing the final report for this project.

National Sample Survey of Registered Nurses. For this large mail survey, wrote the sampling program and designed a multiple use interactive receipt control system allowing direct access to the data. Because the sampling program for this project was nationwide, it required 50 unique formats for the states involved. The sample size for this project was 45,000. The receipt control system allowed the use of an optical character reading (OCR) wand to enter data into the system. Calculating weights and variances, using jackknife methods, for this project.

Relevant Experience (Cont'd.)

Basic Educational Opportunity Grants (Pell Grants) Quality Control Study. Conducted a number of programming tasks for this study designed to create, install and test a quality control system for the Pell Grant Program. Designed a SAS macro for the U.S. Department of Education on this project. The macro allowed flexible interface between the program and the system to provide information and generate new information. The macro system generated different outputs, including variances to create 42 tables. Wrote eight SAS programs to generate weights and calculate variances on this project. Worked on the earlier stages of the study during the data collection segment. Produced tabulations and standard error calculations based on a half sample replicate technique.

Editing, Data Processing and Random Digit Dialing for Cancer and Steroid Hormone Study (CASH). Wrote a series of programs in SAS to derive variables from the analysis files of this case/control study designed to examine the relationship between steroid hormones and three types of cancer. These variables were created for the Centers for Disease Control (CDC) to use in future statistical processing.

Hispanic Health and Nutrition Examination Survey (HHANES). For HHANES, set up the sample frame and drew the sample using data from the 1980 Census of Population. The sample was drawn from approximately 23 counties con- taining 80 percent of the national Hispanic population. This study conducted for the National Center for Health Statistics (NCHS) was the first large-scale examination study of the Hispanic population in the U.S. Produced summaries of the expected sample yield for the sites as part of the overall system of survey management.

Support Services for Epidemiologic/Field Studies. Worked on the following studies under this contract for the National Cancer Institute.

- **Special Study of the Role of Saccharin in Bladder Cancer of the General Population.** Updated the analysis file for this project, and produced various crosstabulations and stratified analyses of case/control data (ODDS-Risque runs). Over 10,000 questionnaires were processed for this study.
- **Florida Colon Cancer Study.** Produced summary reports for the survey management system of this project. Designed and developed program to create and analyze a preliminary data base to produce cross-tabulations and statistical reports. Westat's computer assisted telephone interviewing system was used for the interviewing component of this project. Made presentations at NCI and Westat on the CATI data structures. At the completion of the collection stage of the survey, wrote programs to edit, update and transform the CATI system data structure to deliverable OS and SAS files.

Comprehensive Disease Statistics Survey Feasibility Study. Implemented and maintained the 13 disease specific data editing systems for this study conducted for the National Institute for Neurological and Communicative Disorders and Stroke. For this study, data were collected from the medical records of about 1,000 persons with 2,300 stays sampled from 27 hospitals. Designed and implemented analyses programs to produce summary statistics for the methodology report and several disease-specific reports.

CURRICULUM VITAE
CARLENE ANDERSON

Education

1985 Tumor Registry Certification

1984-88 General Studies Course Work
Southeast Missouri University
Cape Girardeau, MO 63701

1976 Medical Terminology Course Work
Cape Girardeau Vocational-Technical School
Cape Girardeau, MO 63701

Work Experience

1988-Present Survey Research Associates, Inc.
St. Louis, MO 63124

TUMOR REGISTRY COORDINATOR: Case/Control Study of Residential Exposure to Radon. Contacts hospitals throughout the State of Missouri several times a month to encourage rapid case ascertainment of prospective cases. Makes circuit trips to hospitals to abstract records for possible eligibility in the study. Reviews abstracts sent to the Cancer Registry in Columbia, Missouri to make certain that they are complete and accurate, and assigns the necessary coding and staging. For retrospective cases, accesses files and microfiche to ascertain cases for inclusion in the study. Completes abstract forms for retrospective cases. Refers all cases to Survey Research Associates, Inc. for screening. *(Client: National Cancer Institute and Missouri Department of Health)*

1983 - 1988 Southeast Missouri Hospital
Cape Girardeau, MO 63701

CERTIFIED TUMOR REGISTRAR: In charge of maintaining the tumor registry. Supervised one full-time and one part-time employee. Abstracted cancer charts. Arranged tumor committee meetings and tumor conferences. Conducted lifetime surveillance on cancer patients. Corresponded with other hospitals, doctors and patients.

1977 - 1983 St. Francis Medical Center
Cape Girardeau, MO 63701

TUMOR REGISTRAR/UTILIZATION REVIEW COORDINATOR: Worked as tumor registrar and follow-up secretary. Abstracted cancer charts. Assisted in the arrangement of tumor committee meetings and tumor conferences. Conducted lifetime follow-ups for cancer patients. Corresponded with other hospitals, doctors and patients.

1976 - 1977 Chaffee General Hospital
Chaffee, MO 63740

INSURANCE CLERK

1975 - 1976 Perry County Memorial Hospital
Perryville, MO 63775

SWITCHBOARD OPERATOR/ADMISSIONS CLERK

Professional Affiliations

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CURRICULUM VITAE

STEVEN M. LIPKIND

Education

1969 M.Ed., University of Missouri, Curriculum Development and Secondary School Administration
1965 B.A., University of Missouri, Art History

Work Experience

1988-Present Survey Research Associates, Inc.
St. Louis, Missouri 63124

HOUSEHOLD CONSTRUCTION CONSULTANT: **Case/Control Study of Residential Exposure to Radon.** Assisted the Project Director on the development of the Household Construction Survey, training procedures and training manual. Conducted the pretest for the Household Construction Survey. Assisted in the training of the field technicians, especially in the area of construction methods. Acted as consultant to the project throughout the fieldwork. *(Client: National Cancer Institute and Missouri Department of Health).*

1989-Present Joseph Bastian and Company (General Contractor)
St. Louis, Missouri

PARTNER AND CHIEF EXECUTIVE OFFICER: Responsibilities included hiring, training and supervising technicians and workmen, customer relations, acquiring new accounts, and estimating construction work to be done.

1983 - 1988 Steve Lipkind Construction Company
St. Louis, Missouri

PRESIDENT AND CHIEF EXECUTIVE OFFICER: Created new business enterprise, provided leadership for the $750,000 annual volume company. Responsibilities included hiring, training and supervising technicians and workmen, customer relations, acquiring new accounts, and estimating work to be done.

1980 - 1983 Dubman Construction
St. Louis, Missouri

GENERAL MANAGER: Responsibilities included project management, sales, estimating costs for residential and commercial projects, rehab and renovation, ordering materials, scheduling workers, and customer relations.

1974 - 1980 Jourman Remodeling Company
St. Louis, Missouri

GENERAL MANAGER: Responsibilities included project management, sales, estimating costs for residential and commercial projects, rehab and renovation, ordering materials, scheduling workers, and customer relations.

1970 - 1974 Soldan High School
St. Louis, Missouri

ASSISTANT PRINCIPAL: Responsibilities included coordinating curriculum, arranging academic schedules of all students and faculty, coordinating all grade reporting, preparing and writing state, federal and North Central Accreditation annual reports. *(Student body: 4,100 / Faculty: 119)*

1969 - 1974 St. Louis Public School District and
University City Public School District

Taught adult evening education classes for both school districts. Subjects taught included english, literature, mathematics, science and social studies.

1965 - 1970 Soldan High School
St. Louis, Missouri

Taught history and economics. Developed and wrote consumer economics curriculum for school district.